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(54) Title: WOUND TREATMENT APPARATUS AND METHOD

(57) Abstract: An apparatus for cleansing wounds with means for applying flow stress to the wound bed; and in which irrigant fluid from a reservoir connected to a conformable wound dressing and wound exudate from the dressing are moved by a device (which may be a single pump or two pumps) for moving fluid through a flow path which passes through the dressing and a means for providing simultaneous aspiration and irrigation of the wound, and means for applying flow stress to the wound bed. The former removes materials deleterious to wound healing, while distributing materials that are beneficial in promoting wound healing over the wound bed. The latter promotes wound healing. The dressing and a method of treatment using the apparatus.

WOUND TREATMENT APPARATUS AND METHOD

The present invention relates to apparatus and a medical wound dressing for aspirating, irrigating and/or cleansing wounds, and a method of treating wounds using such apparatus for aspirating, irrigating and/or cleansing wounds.

It relates in particular to such an apparatus, wound dressing and method that can be easily applied to a wide variety of, but in particular chronic, wounds, to cleanse them of materials that are deleterious to wound healing, whilst distributing materials that are beneficial in some therapeutic aspect, in particular to wound healing.

Aspirating and/or irrigating apparatus are known, and tend to be used to remove wound exudate during wound therapy. In known forms of such wound therapy, aspiration and irrigation of the wound generally take place sequentially.

Each part of the therapy cycle is beneficial in promoting wound healing.

Aspiration applies a negative pressure to the wound, which is beneficial in itself in promoting wound healing by removing materials deleterious to wound healing with the wound exudate, reducing bacterial load, combating peri-wound oedema, increasing local blood flow to the wound and encouraging the formation of wound bed granulation tissue.

Irrigation cleanses wounds of materials that are deleterious to wound healing by diluting and moving wound exudate, which is typically relatively little fluid and may be of relatively high viscosity and particulate-filled.

Additionally, relatively little of beneficial materials involved in promoting wound healing (such as cytokines, enzymes, growth factors, cell matrix components, biological signalling molecules and other physiologically active components of the exudate) are present in a wound, and are not well distributed in the wound, i.e. they are not necessarily present in parts of the wound bed where they can be potentially of most benefit. These may be distributed by irrigation of the wound and thus aid in promoting wound healing.

The irrigant may additionally contain materials that are potentially or actually beneficial in respect of wound healing, such as nutrients for wound cells to aid proliferation, and gases, such as oxygen. These may be distributed by irrigation of the wound and thus aid in promoting wound healing.

If aspiration and irrigation therapy is applied sequentially to a wound, the two therapies, each of which is beneficial in promoting wound healing, can only be applied intermittently.

Thus, the wound will lose the abovementioned known beneficial effects of aspiration therapy on wound healing, at least in part, while that aspiration is suspended during irrigation.

Additionally, for a given aspirate flow, whilst materials that are potentially or actually deleterious in respect of wound healing are removed from wound exudate, the removal in a given time period of application of the total irrigate and/or aspirate therapy will normally be less effective and/or slower than with continuous application of aspiration.

Even less to be desired, is that while aspiration is not applied to the wound, wound exudate and materials deleterious to wound healing (such as bacteria and debris, and iron II and iron III and for chronic wounds proteases, such as serine proteases) will pool on the wound bed and hinder wound healing, especially in a highly exuding wound. The influx of local oedema will also add to the chronicity of the wound. This is especially the case in chronic wounds.

Depending on the relative volumes of irrigant and wound exudate, the mixed exudate-irrigant fluid and may be of relatively high viscosity and/or particulate-filled. Once it is present and has pooled, it may be more difficult to shift by the application of aspiration in a conventional sequential aspirate – irrigate – dwell cycle than with continuous simultaneous aspiration and irrigation of the wound, owing to the viscosity and blockage in the system.

The wound will also lose the abovementioned beneficial effects of irrigation therapy on wound healing, at least in part, while that irrigation is suspended during aspiration.

These benefits in promoting wound healing include the movement of materials that are beneficial in promoting wound healing, such as those mentioned above.

Additionally, for a given irrigant flow, the cleansing of the wound and the distribution by irrigation of the wound of such beneficial materials in a given time period of application of the total irrigate and/or aspirate therapy when such therapy is in a conventional sequential aspirate – irrigate – dwell cycle will normally be less effective and/or slower than with continuous application of aspiration.

Such known forms of aspiration and/or irrigation therapy systems also often create a wound environment that may result in the loss of optimum performance of the body's own tissue healing processes, and slow healing and/or in weak new tissue growth that does not have a strong three-dimensional structure adhering well to and growing from the wound bed. This is a significant disadvantage, in particular in chronic wounds.

The relevant devices tend not to be portable.

It thus would be desirable to provide a system of aspiration and irrigation therapy for a wound, which
can remove wound exudate and materials deleterious to wound healing from contact with the wound bed,
whilst simultaneously cleansing it and distributing materials that are beneficial in promoting wound healing across it.

It is desirable to provide a system which is:

a) Obviates at least some of the abovementioned disadvantages of known aspiration and/or irrigation systems, and
b) is portable.

Vascular supply to, and aspiration in, tissue underlying and surrounding the wound is often compromised.

It is further desirable to provide a system of therapy that also promotes vascular supply to tissue underlying and surrounding a wound, promoting wound healing.

Additionally, known forms of wound dressing and aspiration and/or irrigation therapy systems often create a wound environment under the backing layer that may result in the loss of optimum performance of the body's own tissue healing processes, and slow healing and/or weak new tissue growth that does not have a strong three-dimensional structure adhering well to and growing from the wound bed. This is a significant disadvantage, in particular in chronic wounds.

It is an object of the present invention to provide a system of therapy which

i) can remove materials deleterious to wound healing from wound exudate, and

ii) which creates flow stress across the wound bed surface, e.g. a shear flow gradient, e.g. by passing irrigant and/or wound exudate through the wound in a controllable stream.

Such a flow stress across a cell containing surface such as the wound bed, e.g. a shear flow gradient, has been found to result in effects that may be beneficial for wound healing.

The motion of fluids across a surface results in shear stresses within the surface. On a micropscopic level such flow may cause other localised or general forces on areas of the surface. These forces or stresses are encompassed in the term flow stress as used herein.

These are effects such as, but not limited to an increase in cell proliferation, debridement of necrotic tissue, removal of slough and to allow alignment of collagen fibres.

This leads to improved breaking strength of tissue growth, to a strong three-dimensional structure adhering well to and growing from the wound bed, and reduction of wound recurrence.

The application of flow stress to a wound is equally applicable to both sequential systems (i.e. empty/fill cycles) or simultaneous irrigate/aspirate systems. Although it is generally preferred to use a simultaneous system, due to the benefits of such a system, there may be circumstances where a sequential system is preferred, e.g. due to cost.

Removal of excess fluid assists with the reduction of interstitial oedema and pressure directly affecting the lymphatic and capillary system, restoring lymph function and stimulating blood flow.

Thus, according to the present invention there is provided an apparatus for aspirating, irrigating and/or cleansing wounds, comprising

a) a fluid flow path, comprising a conformable wound dressing, having a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound and at least one pipe, which passes through and/or under the wound-facing face, to allow irrigation and/or aspiration of the wound, wherein the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound wherein use;

b) a fluid reservoir connected by a fluid supply tube to the at least one pipe; and

c) at least one device for moving fluid through the wound dressing to the wound and/or moving fluid from the wound;

characterised in that the apparatus comprises

d) means for applying flow stress to the wound bed.

Generally it is preferred that the apparatus has at least one inlet pipe for connection to a fluid supply tube to allow irrigation and at least one outlet pipe for connection to a fluid offtake tube to allow aspiration each of which passes through and/or under the wound-facing face.

In one embodiment the present invention provides means for providing simultaneous aspiration and irrigation of the wound, such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (optionally via means for supply flow regulation) while fluid is aspirated by a device through the fluid offtake tube (optionally or as necessary via means for aspirate flow regulation).

Such an embodiment is suitable for simultaneous irrigation and aspiration and thus forms a preferred embodiment of the present invention.

Where any pipe is described in connection with the apparatus as being connected or for connection to a (mating end of a) tube, e.g. a fluid supply tube or fluid offtake tube, the pipe and the tube may form a single integer in the flow path.

The means for applying flow stress to the wound bed in the apparatus for aspirating, irrigating and/or cleansing a wound according to the first aspect of the present invention include means for applying, controlling and/or varying fluid (i.e. irrigant and/or wound exudate) flow under the wound dressing as hereinbefore defined at any appropriate points across the wound bed.

These include

a) features in the conformation of the wound dressing, in particular in the wound facing face of the dressing in relation to the wound bed in use, and/or

b) features in the rest of the system in which the fluid moves, in particular the throughput of the device for moving fluid through the wound

which give the appropriate or desired fluid flow rate or velocity of the irrigant and/or wound exudate under the wound dressing to cause flow stress at any appropriate points across the wound bed. These are described in detail hereinafter in connection with the operation of the apparatus.

It is sufficient to note here that features in the conformation of the wound dressing, in particular in the wound facing face of the dressing in relation to

the wound bed in use, which give the appropriate or desired fluid flow rate or velocity of the irrigant and/or wound exudate under the wound dressing to cause flow stress at any appropriate points across the wound bed include irrigant inlet manifolds which contact or lie very close to the wound bed, irrigant inlet or outlet manifolds comprised in the dressing, which have apertures or pores by the wound bed that are of suitable total area over an extended area, projections, such as bulges or protuberances on the wound-facing face of the dressing, that are capable of directing flow.

Features in the rest of the system in which the fluid moves, in particular the throughput of the device for moving fluid through the wound, which give the appropriate or desired fluid flow rate or velocity of the fluid (i.e.irrigant and/or wound exudate) under the wound dressing to cause flow stress at any appropriate points across the wound bed include devices which impose:

- relatively high flow rates or velocities, or rates of change in the flow rates or velocities, of irrigant and/or wound exudate flow under the wound dressing at any appropriate points across the wound bed; and/or
- a relatively high pressure drop between the interior of an inlet manifolds comprised in the dressing and the wound bed.

Change in the flow velocities of fluid (i.e. irrigant and/or wound exudate) flow under the wound dressing at any appropriate points across the wound bed include changes from positive to negative over the wound bed, i.e. reversing flow, in particular with relatively high rates of flow across the wound bed.

As noted hereinbefore, the present invention in this aspect advantageously provides a means for combining more than one therapy in a single dressing system, such as

a) removal of materials deleterious to wound healing from wound exudate, and
b) promoting wound healing, by stimulating new tissue growth adhering well to and growing from the wound bed, by creating flow stress across the wound bed surface.

Such flow stress across the wound bed may also advantageously act against wound bacteria, by

a) breaking up biofilm growth before it develops a strong three-dimensional structure adhering well to and growing from the wound bed and/or
b) releasing them to be attacked by the body in the wound.

It may aid in the debridement of slough, eschar and necrotic tissue growth from the wound, and in preventing adhesion of wound tissue to the dressing.

Examples of suitable ways in which flow stress can be achieved include applying

a) an optionally varying and/or reversing linear flow and/or
b) a relatively high rate of irrigant flow

across the area of the wound bed.

That is, flow stress across the wound may be provided by means of

a) a linear flow of irrigant across the wound bed,
b) a relatively high rate of irrigant flow across the wound bed, or
c) a combination of the two.

Generally simultaneous irrigate/aspirate systems lead themselves to including flow stress as fluid can be induced to flow between an inlet and outlet as required (this is described in more detail below). However, sequential systems are also suitable for inducing flow stresses. In particular these stresses may be induced during the filling and emptying cycles.

When used herein, the term 'linear' refers to flow that is locally linear on a cellular scale, and thus includes not only parallel flow, but also radial streaming, and spiral, helical, spirohelical and circular streaming. Preferred linear flows include radial streaming from the centre out and from the periphery in to centre, in particular from the periphery in to the centre as this may increase the cell motility velocity of keratinocytes towards the centre, and so promote re-epithelialisation.

It is also preferred that the flow rate is relatively uniform across the wound to achieve a uniform stimulation applied across the wound bed.

The velocity of the fluid thereover may be constant, but it may be varied, preferably cyclically, either randomly or regularly. Usually the direction of the wound irrigant and/or wound exudate is held constant, but the flow rate may be varied positively and negatively, preferably cyclically, and either randomly or regularly.

Cyclical application of flow stress across the wound bed may result in a further increase in cell proliferation and in the breaking strength of tissue growth, and in a strong three-dimensional structure of tissue adhering well to and growing from the wound bed.

The stimulation of the healing of wounds in the present invention may also be effected by regularly or randomly pulsing a flow velocity applied to the wound at any appropriate point for this purpose.

The frequencies of such pulsed flow stressing across the wound will be

a) substantially higher than those of the cycles of flow velocity to the wound bed for the stimulation of the healing of wounds referred to above, but
b) less (generally substantially less) than the frequencies of ultrasound that may be used on the wound bed in alternative methods of therapy.

Pulsing the flow over the wound may advantageously also provide a means to over-ride pain, similar to TENS

Stimulus to the wound bed by applying an optionally varying flow velocity (i.e. cyclical) and agitation of the wound bed to stimulate the cells by regularly or randomly pulsing any flow applied to the wound are mutually compatible. They may, as appropriate, be applied alone or together. Flow may be applied continually or in periodic episodes between which the apparatus is operating in lower flow regimes, or indeed where the apparatus is working on a sequential (fill/empty) basis.

Thus, an embodiment of the apparatus for irrigating, flow stressing and/or cleansing wounds of the present invention is characterised in that it comprises means for supplying optionally varying linear flow velocity, which is optionally pulsed, to a wound bed for the stimulation of the healing of the wound.

Examples of suitable linear velocities are up to 0.03 m/s in a 100 micrometre gap or channel between wound bed and dressing creating a shear stress on the wound bed of the order of 12 - 13 dynes/cm^2. In practice, such a velocity will be of the order of 0.06 to 6, e.g. 0.2 to 2, for example 0,6 mm/s in a 100 micrometer channel between wound bed and dressing creating a shear stress on the wound bed of the order of 0.06 to 20, e.g. 0.6 to 6, for example 0.6 - 2 dynes/cm^2, for a typical wound exudate and/or isotonic saline irrigant.

By way of example, a fluid velocity of e.g. 0.3 m/s will typically be a flow rate of 70 – 200ml/hr for a 100 mm diameter wound.

It will be appreciated that the shear stress (and consequentially flow stress) on the wound bed will increase with the viscosity of the fluid passing across it. This property may be used to increase or decrease the flow stress generated by a given flow velocity.

Another embodiment of the apparatus for irrigating, flow stressing and/or cleansing wounds of the present invention is characterised in that it comprises means for supplying optionally varying relatively high flow velocity, which is optionally pulsed, to a wound bed for the stimulation of the healing of the wound.

As noted hereinbefore, in the present invention in this aspect, the flow velocity of the fluid may be constant, but may be varied, preferably cyclically, either randomly or regularly. In both embodiments:

Examples of suitable frequencies of such regular cycles of flow velocities for the stimulation of the healing of wounds include 1 to 48 per 24 hr.

Examples of preferred frequencies of such regular cycles of flow velocities for the stimulation of the healing of wounds include 12 to 24 per 24 hr, e.g. 2 to 1 per hr.

Examples of suitable waveforms of such cycles either regularly or randomly for the stimulation of the healing of wounds include curved, e.g. sinusoidal, and sawtooth for higher frequencies, and usually square for lower frequencies.

Examples of means for applying flow stress to the wound bed include supplying irrigant to, and letting out irrigant and/or wound exudate from, the wound dressing in regular or random cycles and/or pulsed either regularly or randomly.

Examples of suitable frequencies of such regular pulses for the stimulation of the healing of wounds include 1 to 60 per min, e.g. 5 to 10 per min.

Examples of preferred frequencies of such regular pulses for the stimulation of the healing of wounds include 30 to 60 per min, e.g. 10 to 20 per min.

Examples of suitable waveforms of such pulses either regularly or randomly for the stimulation of the healing of wounds include curved, e.g. sinusoidal, sawtooth, square and a systolic-diastolic asymmetric sawtooth.

Examples of means for applying an optionally varying linear flow velocity at any appropriate point for flow stressing the wound include a wound dressing as hereinbefore described defined that comprises one or more modules capable of imposing linear flow on the irrigant at any appropriate point across the wound bed.

Thus, one favoured embodiment of the apparatus for irrigating, stressing and/or cleansing wounds is characterised in that it comprises a wound dressing as hereinbefore defined that comprises one or more modules capable of imposing linear flow on the irrigant across the wound bed at any appropriate point for flow stressing the wound.

Examples of suitable modules capable of imposing linear flow on the irrigant across the wound bed at any appropriate point for stressing the wound include the following in conjunction with a wound-facing face of the dressing that is in contact with or very close to the wound bed.

A plurality of inlet and/or outlet pipes maybe disposed in an array under the wound-facing face of the dressing, so as to allow passage of irrigant and/or wound exudate through the wound to take place in a controllable linear stream.

Irrigant inlet and/or outlet manifolds with respectively a plurality of inlet and/or outlet apertures, and connected in turn to at least one irrigant inlet pipe(s) and/or outlet pipe(s) may be provided under the wound-facing face of the wound dressing. (Fluid passes between these structures and they assist in channelling flow of irrigant and/or wound exudate through the wound in a controllable stream.) These may, for example, include tubules in an array connecting into a manifold.

Projections, such as bulges or protruberances, may be provided on the wound-facing face of the dressing. Alternatively or additionally, where appropriate depressions may be provided on the wound-facing face of the dressing.

Both will often run within the wound between the inlet pipe(s) and the outlet pipe(s) (or manifolds) under the wound-facing face of the wound dressing.

Fluid-inflatable bodies that lie in the wound in use and form projections are described hereinafter in greater detail.

Of particular interest are fluid-inflatable irrigant inlet manifolds comprised in the dressing, which are inflated by admitting irrigant fluid.

Examples of preferred such modules include fluid-inflatable irrigant inlet manifolds comprised in the dressing as described hereinafter in greater detail.

The modules and backing layer may be completely separate integers, separate integers which are attached, for example by heat sealing, to each other, or they may be integral, i.e. may be formed of a single piece of material.

In all cases the modules may be disposed to impose linear flow between the inlet pipe(s) (or manifold) and the outlet pipe(s) (or manifold) under the wound-facing face of the wound dressing, as hereinbefore describe, in a number of different modes.

Examples of forms of linear flow imposed on the irrigant across the wound bed at any appropriate point for stressing the wound include not only parallel flow, but also radial streaming, and spiral, helical, spirohelical and circular streaming. Preferred linear flows include radial streaming. Preferred linear flows include radial streaming from the centre out and from the periphery in to centre, in particular from the periphery in to the centre as this may increase the cell motility velocity of keratinocytes towards the centre, and so promote re-epithelialisation.

Thus, the modules may comprise a plurality of inlet and/or outlet pipes (or manifold(s)) disposed in an array under the wound-facing face of the dressing, so as to allow passage of irrigant and/or wound exudate through the wound to take place in a controllable linear stream.

Two arrays of inlet pipe(s) and/or outlet pipe(s) (or manifold(s)) under the wound-facing face of the wound dressing may be aligned parallel to each other, opposing each other diametrically across the wound, so that when fluid passes between these structures they assist in channelling flow of irrigant and/or wound exudate across the wound in a parallel stream.

Preferably, a plurality of inlet pipe(s) or outlet pipe(s) (or manifold(s)) is disposed to surround respectively one or more centrally disposed outlet or inlet pipes. (These may be at the geometric centre of the backing layer of the wound dressing as hereinbefore defined, rather than generally centrally disposed therein.) The purpose is to allow passage of irrigant and/or

wound exudate through the wound to take place in a controllable radial stream. Such a stream applies flow stress radially across the wound bed. The plurality of inlet and/or outlet pores or apertures respectively in irrigant inlet and/or outlet manifolds, connected in turn to at least one irrigant inlet pipe(s) and/or outlet pipe(s) under the wound dressing can be considered as equivalent to the above plurality of inlet pipe(s) or outlet pipe(s). Again, the purpose is to allow passage of irrigant and/or wound exudate through the wound to take place in a controllable linear stream.

As above, such irrigant inlet and/or outlet manifolds may be aligned parallel to each other, opposing each other diametrically across the wound, so that when fluid passes between these structures they assist in channelling flow of irrigant and/or wound exudate across the wound in a parallel stream. Alternatively they may be arranged in a concentric arrangement or similar wherein an inlet/outlet manifold surrounds a corresponding inlet/outlet manifold.

Preferably, an irrigant inlet and/or outlet manifold with respectively a plurality of inlet and/or outlet apertures is disposed to surround respectively at least one more-centrally disposed outlet or inlet pipes. (These may be at the geometric centre of the backing layer of the wound dressing as hereinbefore defined, rather than generally centrally disposed therein.)

Preferably, an irrigant outlet and/or inlet manifold with respectively a plurality of inlet and/or outlet pores or apertures is connected respectively to the at least one more-centrally disposed outlet or inlet pipes.

The purpose in both cases is to allow passage of irrigant and/or wound exudate through the wound to take place in a controllable radial stream. As above, such a stream applies flow stress radially across the wound bed.

As noted above, such irrigant inlet manifolds may be fluid-inflatable bodies that lie in the wound in use and form projections, as described hereinafter in greater detail.
These are inflated by admitting irrigant fluid, and they assist in channelling flow of irrigant and/or wound exudate through the wound.

In all such cases of radial streaming, the surrounding apertures could be at or near the periphery of the wound-facing face of the dressing, and the more-centrally disposed apertures could be at or near the centre. However, each are often disposed regularly or irregularly across the dressing, in the manner of a shower-head, and they are preferably disposed regularly across it, as this favours a constant flow rate over all parts of the wound bed.

Thus, according to another embodiment of the first aspect of the present invention there is provided a apparatus for irrigating and/or cleansing wounds, characterised in that it comprises a conformable wound dressing as hereinbefore defined having at least one (and preferably a plurality) of inlet or outlet apertures more-centrally disposed therein and a plurality of respectively outlet or inlet apertures disposed to surround the more-centrally disposed apertures.

The apertures may include the outlets of tubules of an array connecting into a manifold. More usually, however, in all embodiments comprising such manifolds, they are formed of porous film or microporous membrane.

The apertures or pores by the wound bed are preferably distributed evenly over the underside of the dressing and/or over the wound bed in use. To achieve a relatively high flow rate, and depending on the appropriate or desired flow rate, of the moving fluid over the wound bed, the apertures or pores by the wound bed may suitably form of the order of 0.5 to 30% of the area of the wound-facing face of the dressing by the wound bed, such as 0.7 to 10%, e.g. 0.9 to 3%, for example about 1%.

They may have an average cross-dimension of 1 to 1000μm, such as 3 to 300μm, e.g. 5 to 100μm, for example 6 to 60μm.

To the same end, in the present invention, the pressure differential across the porous film or microporous membrane with the apertures or pores by the wound bed on the underside of the dressing in use may suitably be of the order of 1 to 500 mmHg, such as 3 to 250 mmHg, e.g.10 to 125 mmHg, for example about 80 mmHg.

Alternatively or additionally, where appropriate there may be projections, such as bulges or protruberances, and/or where appropriate depressions, effectively on the wound-facing face of the dressing. Both will often run within the wound between the inlet pipe(s) and the outlet pipe(s) under the wound-facing face of the wound dressing. (Fluid passes between these structures and they assist in channelling flow of irrigant and/or wound exudate through the wound in a controllable stream.)

The projections may have a significantly three-dimensional structure, such as points, bosses, ribs and ridges.

Such bosses may be circular, elliptical or polygonal in plan view, such as triangular, rectangular or hexagonal.

These may be may be, e.g. an integral net with elongate apertures e.g. formed by fibrillation of an embossed film, sheet or membrane of a polymeric material or by casting the material.

These are preferably projections in a substantially radiating array under the wound-facing face of the wound dressing. The projections may be disposed regularly or irregularly across the dressing, although they are often disposed regularly across it.

Again, the depressions may have a significantly three-dimensional structure, such as grooves, channels or conduits. In all cases, the structures are preferably in a substantially radial array. Suitably, these may be formed by embossing a sheet, film or membrane.

It will be apparent that any features of inflation of the wound facing face of the dressing may be used to help direct or guide fluid flow to provide linear flow.

Fluid-inflatable bodies that lie in the wound in use may form such projections, in particular such inlet manifolds, as described hereinafter in greater detail. These are inflated by admitting irrigant fluid, and they assist in channelling flow of irrigant and/or wound exudate through the wound in a

controllable stream. As noted above, they may be formed of porous film or microporous membrane.

The inflated manifolds may have a significantly three-dimensional structure, such as points, bosses, ribs and ridges. Such bosses may be circular, elliptical or polygonal in plan view, such as triangular, rectangular or hexagonal.

The backing layer and modules may be of the same or different materials, but each should be of a material that does not absorb aqueous fluids such as water, blood, wound exudate, etc. and is soft and resiliently deformable.

According to another embodiment of the present invention there is provided a apparatus for irrigating and/or cleansing wounds, characterised in that it comprises a conformable wound dressing as hereinbefore defined having projecting or depressed structures disposed between the inlet pipe(s) and the outlet pipe(s) under the wound-facing face of the wound dressing.

In the embodiment of the apparatus that is characterised in that it comprises means for supplying optionally varying flow velocity, which is optionally pulsed, to a wound bed for the stimulation of the healing of the wound, the relatively high flow rates are typically provided by the device for moving fluid through the wound.

The type and/or capacity of a suitable device for moving fluid through the wound at the desired velocity will be largely determined by the appropriate or desired fluid flow rate and the flow resistance of the flow path.

Suitable devices are indicated below.

As noted hereinbefore, in all embodiments of this aspect of the present invention, the flow velocity of the fluid may be constant, but may be varied, preferably cyclically, either randomly or regularly.

To achieve this, the present apparatus additionally, where appropriate, comprises a system which can regulate the pump output to the wound bed under the wound dressing.

Preferably such a system is a conventional automated, programmable system which can maintain the wound at or near an appropriate, desired flow stress to the wound bed and regularly or randomly pulse a flow velocity applied to the wound at any appropriate point for this purpose.

Such pulsed flow across the wound may be provided by some types of the device for moving fluid through the wound.

Certain diaphragm pumps described hereinafter in greater detail will be appropriate for this purpose, as are peristaltic pumps, an electrically pulsable valve on the fluid reservoir, and an electromechanical oscillator directly coupled to the wound dressing.

It will of course be apparent that the apparatus of the present invention may comprise more than one of the means described above to induce flow stress. For example the apparatus may have means to vary fluid flow and means to improve linear flow in a desired form.

Where the present invention involves simultaneous irrigation/aspiration it provides several further advantages.

One is that application of an irrigant to a wound under simultaneous aspiration creates a wound environment that is exposed to the continuous beneficial effects of both aspects of the therapy for wound healing, as opposed to the sequential intermittent application of irrigant flow and aspiration in known aspirating and/or irrigating apparatus. The latter result in less than optimum performance of the body's own tissue healing processes, and slower healing and/or weaker tissue growth that does not have a strong three-dimensional structure adhering well to and growing from the wound bed. This is a significant disadvantage, in particular in chronic wounds.

Such a system is particularly suited for removing materials deleterious to wound healing with the wound exudate, reducing bacterial load, combating peri-wound oedema and encouraging the formation of wound bed granulation tissue.

Preferred embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing chronic wounds apply a milder negative pressure than in conventional negative pressure therapy (which is too aggressive for the fragile tissues of many such wounds). This leads to increased patient comfort, and lessens the risk of inflammation of the wound.

The removal of wound exudate in a given time period of application of the simultaneous irrigate and/or aspirate therapy will normally be more effective and/or faster than with a conventional sequential intermittent aspiration and/or irrigation therapy.

Even more desirably, since simultaneous aspiration and irrigation is applied to the wound, wound exudate and materials deleterious to wound healing (such as bacteria and debris, and iron II and iron III and for chronic wounds proteases) will not pool on the wound bed and hinder wound healing. This is especially important in a highly exuding wound and/or in chronic wounds. The resulting mixed exudate-irrigant fluid will usually be of relatively lower viscosity.

Because simultaneous aspiration and irrigation of the wound provides continuous removal at a constant relatively high speed, the fluid does not have to be accelerated cyclically from rest, and will be easier to shift than with known forms of aspiration and/or irrigation therapy systems with a conventional sequential aspirate – irrigate – dwell cycle. This will thus exert a greater net effect on the removal of adherent bacteria and debris.

This is especially the case in those embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds where there is an inlet manifold (as described in further detail hereinafter) that covers and contacts most of the wound bed with

openings that deliver the fluid directly to the wound bed over an extended area.

The present form of aspiration and/or irrigation therapy systems also often create a wound environment for better distribution of materials that are beneficial in some therapeutic aspect, in particular to wound healing, that are present in a wound, but may not be well distributed in the wound, e.g. in a highly exuding wound (These include cytokines, enzymes, growth factors, cell matrix components, biological signalling molecules and other physiologically active components of the exudate), and or materials contained in the irrigant such as nutrients for wound cells to aid proliferation, and gases, such as oxygen.

These may aid wound cell proliferation and new tissue growth that has a strong three-dimensional structure adhering well to and growing from the wound bed. This is a significant advantage, in particular in chronic wounds.

This is especially the case in those embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds where there is an inlet manifold as described below.

An inlet manifold generally covers and contacts a significant area, preferably most, of the wound bed with openings that deliver the fluid directly to the wound bed over an extended area.

It will be seen that the balance of fluid between fluid aspirated from the wound and irrigant supplied to the wound from the irrigant reservoir may provide a predetermined steady state concentration equilibrium of materials beneficial in promoting wound healing over the wound bed. Simultaneous aspiration of wound fluid and irrigation at a controlled flow rate aids in the attainment and maintenance of this equilibrium

The apparatus for irrigating and/or aspirating wounds of the present invention may be used cyclically and/or with reversal of flow.

Preferably the present apparatus for aspirating, irrigating and/or cleansing wounds is a conventionally automated, programmable system which can cleanse the wound with minimal supervision.

The means for providing simultaneous aspiration and irrigation of the wound often comprises

- a (first) device for moving fluid through the wound applied to fluid downstream of and away from the wound dressing, in combination with at least one of
- a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing;
- means for aspirate flow regulation, connected to a fluid offtake tube, and
- means for supply flow regulation, connected to a fluid supply tube;

The (first) device will apply negative pressure (i.e. below-atmospheric pressure or vacuum) to the wound bed. It may be applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing.

Alternatively or additionally, where appropriate, the aspirate in the fluid offtake tube downstream of the wound dressing may be aspirated into a collection vessel, and the first device may act on fluid such as air from the collection vessel. This prevents contact by the device with the aspirate.

The (first) device may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid offtake tube, and/or means for supply flow regulation, connected to a fluid supply tube, in each case, e.g. a regulator, such as a rotary valve.

Alternatively, where appropriate the (first) device for moving fluid through the wound may be a variable-throughput device, such as a variable-speed pump, downstream of the wound dressing, thus effectively forming a combination of a (first) device for moving fluid through the wound with

means for aspirate flow regulation and/or means for supply flow regulation in a single integer.

The (first) device for moving fluid through the wound will often be a pump of any of the types set out below, or a piped supply of vacuum, applied to fluid downstream of and away from the wound dressing. In the case of any pump it may be a fixed-speed pump, with (as above) a discrete means for aspirate flow regulation, connected to a fluid offtake tube, and/or means for supply flow regulation, connected to a fluid supply tube, in each case, e.g. a regulator, such as a rotary valve. Alternatively, where appropriate the pump may be a variable-throughput or variable-speed pump.

The following types of pump may be used as the (first) device:
Reciprocating Pumps, such as

Piston pumps - where pistons pump fluids through check valves, in particular for positive and/or negative pressure on the wound bed; and

Diaphragm Pumps - where pulsations of one or two flexible diaphragm displace liquid with check valves.

and

Rotary Pumps, such as:

Progressing Cavity Pumps - with a cooperating screw rotor and stator, in particular for higher-viscosity and particulate-filled exudate; and

Vacuum Pumps - with pressure regulators.

The (first) device may be a diaphragm pump, e.g. preferably a small portable diaphragm pump. This is a preferred type of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with (chronic) wound exudate, and for ease of cleaning.

Where the pump is a diaphragm pump, and preferably a small portable diaphragm pump, the one or two flexible diaphragms that displace liquid may each be, for example a polymer film, sheet or membrane, that is connected to means for creating the pulsations. This may be provided in

any form that is convenient, inter alia as a piezoelectric transducer, a core of a solenoid or a ferromagnetic integer and coil in which the direction of current flow alternates, a rotary cam and follower, and so on.

Where any second device is applied to the fluid in the fluid supply tube upstream of and towards the wound dressing, it will usually apply positive pressure (i.e. above-atmospheric pressure) to the wound bed.

As with the (first) device, it may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for supply flow regulation, connected to a fluid supply tube, e.g. a regulator, such as a rotary valve.

Alternatively, where appropriate the second device for moving irrigant fluid to the wound may be a variable-throughput device, such as a variable-speed pump, upstream of the wound dressing, thus effectively forming a combination of a second device for moving fluid through the wound with means for supply flow regulation in a single integer.

The second device for moving fluid through the wound will often be a pump of any of the following types applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing. It may be a fixed-speed pump, with (as above) a discrete means for supply flow regulation, connected to a fluid supply tube, e.g. a regulator, such as a rotary valve. Alternatively, where appropriate the pump may be a variable-throughput or variable-speed pump.

The following types of pump may be used as the second device:
Reciprocating Pumps, such as
shuttle pumps - with an oscillating shuttle mechanism to move fluids at rates from 2 to 50 ml per minute
and
Rotary Pumps, such as:
Centrifugal Pumps
Flexible Impeller

Pumps	- where elastomeric impeller traps fluid between impeller blades and a moulded housing that sweeps fluid through the pump housing.
Peristaltic Pumps	- with peripheral rollers on rotor arms acting on a flexible fluid aspiration tube to urge fluid current flow in the tube in the direction of the rotor.
Rotary Vane Pumps	- with rotating vaned disk attached to a drive shaft moving fluid without pulsation as it spins. The outlet can be restricted without damaging the pump.

The second device may be a peristaltic pump, e.g. preferably a small portable peristaltic pump. This is a preferred type of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with irrigant, and for ease of cleaning.

Where the pump is a peristaltic pump, this may be e.g. an Instech Model P720 miniature peristaltic pump, with a flow rate: of 0.2 – 180ml/hr and a weight of < 0.5 k. This is potentially useful for home and field hospital use.

Each such pump of any these types may also suitably be one that is capable of pulsed, continuous, variable and/or automated and/or programmable fluid movement. Less usually and less preferably, each such pump of any these types will be reversible.

As above, the means for supply flow regulation may be a regulator, such as a rotary valve. This is connected between two parts of a fluid supply tube, such that the desired supply flow regulation is achieved.

If there are two or more inlet pipes, these may be connected to a single fluid supply tube with a single regulator, or to first, second, etc. fluid supply tubes, respectively having a first regulator, a second regulator, etc., e.g. a valve or other control device for admitting fluids into the wound.

As above, the means for aspirate flow regulation may be similarly provided in a form in which concomitant aspirate flow regulation is possible. It may be a regulator, such as a valve or other control device, e.g. a rotary valve.

Multiple offtake tubes may be similarly provided with single or multiple regulators, all for aspiration of fluids from the apparatus, e.g. to a aspirate collection vessel, such as a collection bag.

If there is no second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing, it is only possible to apply a negative pressure to the wound, by means of the device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing.

Operation may e.g. be carried out at a negative pressure of up to 50%atm., typically at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound, as is described hereinafter.

Examples of suitable and preferred (first) devices include those types of pump that are so described hereinbefore in relation to the first device. This may be a diaphragm pump, e.g. preferably a small portable diaphragm pump. This is a preferred type of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with (chronic) wound exudate, and for ease of cleaning.

Alternatively, if it is desired to apply a net positive pressure to the wound, the means for providing simultaneous aspiration and irrigation of the wound must comprise not only:

- a first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, but also
- a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing.

Operation may then e.g. be carried out at a positive pressure of up to 50%atm., typically at a low positive pressure of up to 20% atm., more usually up to 10% atm. at the wound, as is described hereinafter.

Examples of suitable and preferred first devices include those types of pump that are so described hereinbefore in relation to the first device. This may be a diaphragm pump, e.g. preferably a small portable diaphragm pump.

Examples of suitable and preferred second devices include those types of pump that are so described hereinbefore in relation to the second device. This may be a peristaltic pump, e.g. a miniature peristaltic pump.

This is a preferred type of pump, in order to eliminate contact of internal surfaces and moving parts of the pump with irrigant in the fluid supply tube upstream of and towards the wound dressing, and for ease of cleaning.

It is of course equally possible to apply a negative pressure to the wound, by means of such a combination of

- a first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, and
- a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing;

optionally with

- means for supply flow regulation, connected to a fluid supply tube; and/or
- means for aspirate flow regulation, connected to a fluid offtake tube.

Indeed, as noted below in this regard, preferred embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing chronic wounds that apply a negative pressure include such types of combination of;

- a first device, e.g. a diaphragm pump, e.g. preferably a small portable diaphragm pump, and

- a second device, e.g. a peristaltic pump, preferably a miniature peristaltic pump,

As noted above, either of the first device and the second device may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid offtake tube, and/or means for supply flow regulation, connected to a fluid supply tube, in each case, e.g. a regulator, such as a rotary valve, or a variable-throughput device, such as a variable-speed pump, downstream of the wound dressing, thus effectively forming a combination of a (first) device for moving fluid through the wound with means for aspirate flow regulation and/or means for supply flow regulation in a single integer.

The higher end of the ranges of % positive and negative pressure noted above are potentially more suitable for hospital use, where they may only be used safely under professional supervision. The lower end is potentially more suitable for home use, where relatively high % positive and negative pressures cannot be used safely without professional supervision, or for field hospital use.

In each case, the pressure on the wound may be held constant throughout the desired length of therapy, or may be varied cyclically in a desired positive or negative pressure regime.

As noted above, when it is desired to apply a negative pressure to the wound, it is preferred that the means for providing simultaneous aspiration and irrigation of the wound comprise not only;

- a (first) device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, but also
- a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing.

Accordingly, one embodiment of the apparatus for irrigating, cleansing and/or aspirating wounds of the present invention is characterised in the

means for providing simultaneous aspiration and irrigation of the wound comprises;

- a (first) device for moving fluid through the wound applied to fluid downstream of and away from the wound dressing, and
- a second device for moving fluid through the wound applied to the I rrigant in the fluid supply tube upstream of and towards the wound dressing, and

in combination with at least one of

- means for supply flow regulation, connected to a fluid supply tube, and
- means for aspirate flow regulation, connected to a fluid offtake tube.

As noted above, either of the first device and the second device may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid offtake tube, and/or means for supply flow regulation, connected to a fluid supply tube, in each case, e.g. a regulator, such as a rotary valve, or a variable-throughput device, such as a variable-speed pump, downstream of the wound dressing, thus effectively forming a combination of a (first) device for moving fluid through the wound with means for aspirate flow regulation and/or means for supply flow regulation in a single integer.

This combination of:

- a device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, and
- a device for moving fluid through the wound applied to the fluid in the fluid supply tube upstream of and towards the wound dressing,

may be used to apply an overall positive or negative, or even zero pressure to the wound.

At least one body in the flow path to, over and from the wound bed should have sufficient resilience against the pressure to allow any significant compression or decompression of the fluid occur.

Thus, examples of suitable bodies include those which are or are defined by a film, sheet or membrane, such as inlet or offtake and/or tubes and

structures such as bags, chambers and pouches, filled with irrigant fluid, and e.g. the backing layer of the wound dressing, made of elastically resilient thermoplastic materials.

It will be seen that the balance of fluid between aspirated fluid from the wound and irrigant supplied to the wound from the fluid reservoir will thus be largely determined by a means for providing simultaneous aspiration and irrigation of the wound which is a system comprising:

a) means for aspirate flow regulation and/or a device for moving fluid through the wound applied to fluid downstream of and away from the wound dressing, and
b) means for supply flow regulation and/or a device for moving fluid through the wound applied to the fluid in the fluid supply tube upstream of and towards the wound dressing.

The same means may be used to apply an overall positive or negative, or even neutral pressure to the wound.

The appropriate flow rate through the supply tube will depend on a number of factors, such as:

- the viscosity and consistency of each of the irrigant, exudate and mixed exudate-irrigant fluid, and any changes as the wound heals;
- the level of negative pressure on the wound bed,
- whether the irrigant in the fluid supply tube upstream of and into the wound dressing is under positive pressure, and the level of such pressure;
- the level of any pressure drop between the irrigant in the fluid supply tube upstream of the wound dressing and the wound bed, such as across a porous element, e.g. a membrane wound contact layer on the lower surface of an inlet manifold that delivers the fluid directly to the wound bed;
- means for supply flow regulation;
- and/or a second device for moving fluid through the wound applied to the fluid in the fluid supply tube upstream of and towards the wound dressing;
- the depth and/or capacity of the wound and

- the power consumption needed for a given desired fluid volume flow rate of irrigant and/or wound exudate through the wound.

The dressing may comprise an inlet manifold (as described in further detail hereinafter) that covers and contacts a significant area, preferably most, of the wound bed with openings that deliver the fluid directly to the wound bed over an extended area, in the form of one or more inflatable hollow bodies defined by a film sheet or membrane. In general a manifold will cover 50% of the wound, preferably 75% or more, though it is possible that it may cover substantially less.

The (usually small) positive pressure above atmospheric from the irrigation device when both devices are running together should be sufficient to inflate the manifold.

The desired fluid volume flow rate of irrigant and/or wound exudate is preferably that for optimum performance of the wound healing process.

The flow rate will usually be in the range of 1 to 1500 ml/hr, such as 5 to 1000 ml/hr, e.g. 15 to 300 ml/hr, such as 35 to 200 ml/hr through the supply tube.

The flow rate through the wound may be held constant throughout the desired length of therapy, or may be varied cyclically in a desired flow rate regime.

In practice, the offtake rate of flow of total irrigant and/or wound exudate will be of the order of 1 to 2000, e.g. 35 to 300 ml/24 hr/cm^2, where the cm^2 refers to the wound area, depending on whether the wound is in a highly exuding state.

In practice, the rate of exudate flow is only of the order of up to 75 microlitres / cm^2/ hr (where cm^2 refers to the wound area), and the fluid can be highly mobile or not, depending on the level of proteases present). Exudate levels drop and consistency changes as the wound heals, e.g. to a level for the same wound that equates to 12.5 – 25 microlitres / cm^2 / hr.

It will be apparent that the aspirated fluid from the wound will typically contain a preponderance of irrigant from the fluid reservoir over wound exudate.

The necessary adjustments to maintain the desired balance of fluid by means of

a) the means for aspirate flow regulation and/or downstream device, and
b) the means for supply flow regulation and/or upstream device for moving fluid

will be apparent to the skilled person, bearing in mind that as noted above, either of the first device and the second device may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid offtake tube, and/or means for supply flow regulation, connected to a fluid supply tube, in each case, e.g. a regulator, such as a rotary valve; or

- a variable-throughput device, such as a variable-speed pump, downstream of the wound dressing, thus effectively forming a combination of a (first) device for moving fluid through the wound with means for aspirate flow regulation and/or means for supply flow regulation in a single integer.

The type and/or capacity of a suitable first and/or second device will be largely determined by

a) the appropriate or desired fluid volume flow rate of irrigant and/or wound exudate from the wound, and
b) whether it is appropriate or desired to apply a positive or negative pressure to the wound bed, and the level of such pressure to the wound bed

for optimum performance of the wound healing process, and by factors such as portability, power consumption and isolation from contamination.

As noted above, when it is desired to apply a negative pressure to the wound with the apparatus of the present invention for aspirating, irrigating and/or cleansing wounds to provide simultaneous aspiration and irrigation

of the wound, the means for providing simultaneous aspiration and irrigation of the wound may comprise

- a single device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing or

in combination with at least one of

- means for supply flow regulation, connected to a fluid supply tube, and
- means for aspirate flow regulation, connected to a fluid offtake tube.

As noted above, the device may be
a fixed-throughput device or a variable throughput device.

In a further aspect the present invention provides a method of operation of an apparatus for aspirating, irrigating and/or cleansing wounds said method comprising the steps of:

a) providing an apparatus as set out above;
b) applying the wound dressing to the wound;
c) conforming the backing layer of the wound dressing to the shape of the bodily part in which the wound is to form a relatively fluid tight seal or closure;
d) activating the at least one device for moving fluid through the wound dressing to the wound and/or from the wound to cause irrigant to move to the wound; and
e) activating the means for applying flow stress to the wound bed.

In a preferred embodiment the apparatus has at least one inlet pipe and at least one outlet pipe, each of which passes through and/or under the wound-facing face. Such an embodiment allows for a method simultaneous and/or sequential irrigation/aspiration of the wound. In such an embodiment step d) of the method comprises activating the at least one device of moving fluid through the wound dressing to move fluid (irrigant) through the at least one inlet and to move fluid (aspirate) out of the at least one outlet pipe.

In a preferred embodiment the irrigant is moved to the wound via the inlet pipe and aspirate removed from the outlet pipe simultaneously i.e. simultaneous irrigation/aspiration. This may be carried out for substantially the entirety of the treatment of the wound, or alternately for portions of the treatment as desired.

Such an embodiment is also suitable for sequential (fill/empty) operation, and thus a method wherein sequential operation is carried out forms an alternative embodiment of the invention. In such an embodiment irrigation would be ceased by ceasing the device moving fluid through the at least one inlet and activating a device to move fluid from the wound through the outlet.

Suitable flow rates and parameters for operation of the means for applying flow stress and for operation of the apparatus in general are set out above. Further details are given below.

The operation of a typical apparatus of this type for simultaneous aspiration and irrigation of a wound at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound, with one pump will now be described. As mentioned previously, the application of negative pressure has benefits for healing.

Before starting the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds, the backing layer of the wound dressing is applied over the wound and conformed to the shape of the bodily part in which the wound is to form a relatively fluid-tight seal or closure.

The means for supply flow regulation, connected to a fluid supply tube, such as a regulator, such as a rotary valve, is usually closed, and the means for aspirate flow regulation (if any), connected to a fluid offtake tube, is opened.

The aspiration pump is started and run to give a negative pressure of up to 50% atm., more usually up to 20% atm., e.g. up to 10% atm. to be applied applies a vacuum to the interior of the dressing and the wound.

The means for fluid supply regulation is opened and is then adjusted, and/or where the aspiration pump is a variable-speed pump, downstream of the wound dressing, that is adjusted, to maintain the desired balance of fluid at a controlled nominal flow rate and to maintain the desired negative pressure in the interior of the wound dressing.

The means for applying flow stress is then activated. Suitable forms of means for applying flow stress are set out above. The means for applying flow stress may be used to apply flow stress constantly or periodically, depending on the desired treatment regime.

The apparatus is then run for the desired length of therapy and with the desired negative pressure and flow stress regime. After this period, the aspiration pump is stopped.

The operation of a typical apparatus for simultaneous aspiration and irrigation of a wound at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound, with two pumps may involve the following.

The necessary changes where the mode of operation is at a net positive pressure of e.g. up to 15% atm., more usually up to 10% atm. at the wound will be apparent to the skilled person.

A typical apparatus for simultaneous aspiration and irrigation of a wound at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound comprises means for providing simultaneous aspiration and irrigation of the wound which is a combination of

a) a first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, with optional means for aspirate flow regulation, connected to a fluid offtake tube: and

b) a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing, with optional means for supply flow regulation, connected to a fluid supply tube.

As noted above, either device may be a fixed-throughput device or a variable throughput device.

Before starting the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds, the backing layer of the wound dressing is applied over the wound and conformed to the shape of the bodily part in which the wound is to form a relatively fluid-tight seal or closure.

Any means for supply flow regulation, connected to a fluid supply tube, such as a regulator, such as a rotary valve, is usually closed, and any means for aspirate flow regulation, connected to a fluid offtake tube, is opened.

The aspiration pump is started and run to apply a negative pressure of up to 50% atm., more usually up to 20% atm., e.g. up to 10% atm., to the interior of the dressing and the wound.

The irrigation pump is then started, so that both pumps are running together, and any means for supply flow regulation is opened.

The irrigation pump flow rate and any means for fluid supply regulation are then adjusted and/or where the aspiration pump and/or the irrigation pump is a variable-speed pump, either or both is/are is adjusted, to maintain the desired balance of fluid at a controlled nominal flow rate and to maintain the desired negative pressure in the interior of the wound dressing.

The means for applying flow stress is then activated, as described above.

The apparatus is then run for the desired length of therapy and with the desired pressure and flow stress regime. After this period, the irrigation pump is stopped, shortly followed by the aspiration pump.

In all embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds, a particular advantage is the tendency of the wound dressing to conform to the shape of the bodily part to which it is applied.

The term 'relatively fluid-tight seal or closure' is used herein to indicate one which is fluid- and microbe-impermeable and permits a positive or negative pressure of up to 50% atm., more usually up to 20% atm., e.g. up to 10% atm. to be applied to the wound. The term 'fluid' is used herein to include gels, e.g. thick exudate, liquids, e.g. water, and gases, such as air, nitrogen, etc.

The shape of the backing layer that is applied may be any that is appropriate to aspirating, irrigating and/or cleansing the wound across the area of the wound.

Examples of such include a substantially flat film, sheet or membrane, or a bag, chamber, pouch or other structure of the backing layer, e.g. of polymer film, which can contain the fluid.

The backing layer may be a film, sheet or membrane, often with a (generally uniform) thickness of up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness.

Its largest cross-dimension may be up to 500 mm (for example for large torso wounds), up to 100 mm (for example for axillary and inguinal wounds), and up to 200 mm for limb wounds (for example for chronic wounds, such as venous leg ulcers and diabetic foot ulcers.

Desirably the dressing is resiliently deformable, since this may result in increased patient comfort, and lessen the risk of inflammation of a wound.

Suitable materials for it include synthetic polymeric materials that do not absorb aqueous fluids, such as polyolefins, such as polyethylene e.g. high-density polyethylene, polypropylene, copolymers thereof, for example with

vinyl acetate and polyvinyl alcohol, and mixtures thereof; polysiloxanes; polyesters, such as polycarbonates; polyamides, e.g. 6-6 and 6 - 10, and hydrophobic polyurethanes.

They may be hydrophilic, and thus also include hydrophilic polyurethanes.

They also include thermoplastic elastomers and elastomer blends, for example copolymers, such as ethyl vinyl acetate, optionally or as necessary blended with high-impact polystyrene. They further include elastomeric polyurethane, particularly polyurethane formed by solution casting.

Preferred materials for the present wound dressing include thermoplastic elastomers and curable systems.

The backing layer is capable of forming a relatively fluid-tight seal or closure over the wound and/or around the inlet and outlet pipe(s).

However, in particular around the periphery of the wound dressing, outside the relatively fluid-tight seal, it is preferably of a material that has a high moisture vapour permeability, to prevent maceration of the skin around the wound. It may also be a switchable material that has a higher moisture vapour permeability when in contact with liquids, e.g. water, blood or wound exudate. This may, e.g. be a material that is used in Smith & Nephew's Allevyn™, IV3000™ and OpSite™ dressings.

The periphery of the wound-facing face of the backing layer may bear an adhesive film, for example, to attach it to the skin around the wound. This may, e.g. be a pressure-sensitive adhesive, if that is sufficient to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound-facing face of the wound dressing.

Alternatively or additionally, where appropriate a light switchable adhesive could be used to secure the dressing in place to prevent leakage. (A light switchable adhesive is one the adhesion of which is reduced by photocuring. Its use can be beneficial in reducing the trauma of removal of the dressing.)

Thus, the backing layer may have a flange or lip extending around the proximal face of the backing layer, of a transparent or translucent material (for which it will be understood that materials that are listed above are amongst those that are suitable). This bears a film of a light switchable adhesive to secure the dressing in place to prevent leakage on its proximal face, and a layer of opaque material on its distal face.

To remove the dressing and not cause excessive trauma in removal of the dressing, the layer of opaque material on the distal face of the flange or lip extending around the proximal wound is removed prior to application of radiation of an appropriate wavelength to the flange or lip.

If the periphery of the wound dressing, outside the relatively fluid-tight seal, that bears an adhesive film to attach it to the skin around the wound, is of a material that has a high moisture vapour permeability or is a switchable material, then the adhesive film, if continuous, should also have a high or switchable moisture vapour permeability, e.g. be an adhesive such as used in Smith & Nephew's Allevyn™, IV3000™ and OpSite™ dressings.

Where a vacuum, is applied to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound-facing face of the wound dressing, the wound dressing may be provided with a silicone flange or lip to seal the dressing around the wound. This removes the need for adhesives and associated trauma to the patient's skin.

Where the interior of, and the flow of irrigant and/or wound exudate to and through, the dressing is under any significant positive pressure, which will tend to act at peripheral points to lift and remove the dressing off the skin around the wound.

In such use of the apparatus, it may thus be necessary to provide securing means for forming and maintaining such a seal or closure over the wound against such positive pressure on the wound, to act at peripheral points for this purpose. Examples of such securing means include light switchable adhesives, as above, to secure the dressing in place to prevent leakage. Since the adhesion of a light switchable adhesive is reduced by

photocuring, thereby reducing the trauma of removal of the dressing, a film of a more aggressive adhesive may be used, e.g. on a flange, as above.

Examples of suitable fluid adhesives for use in more extreme conditions where trauma to the patient's skin is tolerable include ones that consist essentially of cyanoacrylate and like tissue adhesives, applied around the edges of the wound and/or the proximal face of the backing layer of the wound dressing, e.g. on a flange or lip.

Further suitable examples of securing means include adhesive (e.g. with pressure-sensitive adhesive) and non-adhesive, and elastic and non-elastic straps, bands, loops, strips, ties, bandages, e.g. compression bandages, sheets, covers, sleeves, jackets, sheathes, wraps, stockings and hose, e.g. elastic tubular hose or elastic tubular stockings that are a compressive fit over a limb wound to apply suitable pressure to it when the therapy is applied in this way; and inflatable cuffs, sleeves, jackets, trousers, sheathes, wraps, stockings and hose that are a compressive fit over a limb wound to apply suitable pressure to it when the therapy is applied in this way.

Such securing means may each be laid out over the wound dressing to extend beyond the periphery of the backing layer of the wound dressing, and as appropriate will be adhered or otherwise secured to the skin around the wound and/or itself and as appropriate will apply compression (e.g. with elastic bandages, stockings) to a degree that is sufficient to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound,

Such securing means may each be integral with the other components of the dressing, in particular the backing layer.

Alternatively, it may be permanently attached or releasably attached to the dressing, in particular the backing layer, with an adhesive film, for example, or these components may be a Velcro ™, push snap or twist-lock fit with each other.

The securing means and the dressing may be separate structures, permanently unattached to each other.

In a more suitable layout for higher positive pressures on the wound, a stiff flange or lip extends around the periphery of the proximal face of the backing layer of the wound dressing. The flange or lip is concave on its proximal face to define a peripheral channel or conduit. It has a suction outlet that passes through the flange or lip to communicate with the channel or conduit and may be connected to a device for applying a vacuum, such as a pump or a piped supply of vacuum.

The backing layer may be integral with or attached, for example by heat-sealing, to the flange or lip extending around its proximal face.

To form the relatively fluid-tight seal or closure over a wound that is needed and to prevent passage of irrigant and/or exudate under the periphery of the wound-facing face of the wound dressing, in use of the apparatus, the dressing is set on the skin around the wound. The device then applies a vacuum to the interior of the flange or lip, thus forming and maintaining a seal or closure acting at peripheral points around the wound against the positive pressure on the wound.

With all the foregoing means of attachment, and means for forming and maintaining a seal or closure over the wound, against positive or negative pressure on the wound at peripheral points around the wound, the wound dressing sealing periphery is preferably of a generally round shape, such as an ellipse, and in particular circular.

To form the relatively fluid-tight seal or closure over a wound and around the inlet pipe(s) and outlet pipe(s) at the point at which they pass through and/or under the wound-facing face, the backing layer may be integral with these other components.

The components may alternatively just be a push, snap or twist-lock fit with each other, or adhered or heat-sealed together.

The or each inlet pipe or outlet pipe may be in the form of an aperture, such as a funnel, hole, opening, orifice, luer, slot or port for connection as a female member respectively to a mating end of a fluid tube and/or fluid supply tube (optionally or as necessary via means for forming a tube, pipe or hose, or nozzle, hole, opening, orifice, luer, slot or port for connection as a male member respectively to a mating end of a fluid tube and/or fluid supply tube (optionally or as necessary via means for supply flow regulation) or a fluid offtake tube.

Where the components are integral they will usually be made of the same material (for which it will be understood that materials that are listed above are amongst those that are suitable).

Where, alternatively, they are a push, snap or twist-lock fit, the may be of the same material or of different materials. In either case, materials that are listed above are amongst those that are suitable for all the components.

The or each pipe will generally pass through, rather than under the backing layer. In such case, the backing layer may often have a rigid and/or resiliently inflexible or stiff area to resist any substantial play between the or each pipe and the or each mating tube, or deformation under pressure in any direction.

It may often be stiffened, reinforced or otherwise strengthened by a boss projecting distally (outwardly from the wound) around each relevant tube, pipe or hose, or nozzle, hole, opening, orifice, luer, slot or port for connection to a mating end of a fluid tube and/or fluid supply tube or fluid offtake tube.

Alternatively or additionally, where appropriate the backing layer may have a stiff flange or lip extending around the proximal face of the backing layer to stiffen, reinforce or otherwise strengthen the backing layer.

Where a simple pipe is used to supply the irrigant to the wound, this may not provide a system to distribute irrigant over a sufficient functional surface area to irrigate the wound at a practical rate to be suitable for use, in

particular in chronic wound aspiration and irrigation, which may contain relatively high concentrations of materials that are deleterious to wound healing.

It may be advantageous to provide a system where wound irrigant may be distributed more evenly, or pass in a more convoluted path under the dressing over the wound bed.

Accordingly, one form of the dressing is provided with a 'tree' form of pipes, tubes or tubules that radiate from an inlet manifold to the wound bed to end in apertures and deliver the aspirating fluid directly to the wound bed via the apertures. Similarly, there is optionally an outlet manifold from which tubules radiate and run to the wound bed to end in openings and collect the fluid directly from the wound bed.

The pipes, etc. may radiate regularly or irregularly through the wound in use, respectively from the inlet or outlet manifold, although regularly may be preferred. A more suitable layout for deeper wounds is one in which the pipes, etc. radiate hemispherically and concentrically, to the wound bed.

For shallower wounds, examples of suitable forms of such layout of the pipes, etc. include ones in which the pipes, etc. radiate in a flattened hemiellipsoid and concentrically, to the wound bed.

Other suitable forms of layout of the pipes, etc. include one which have pipes, tubes or tubules extending from the inlet pipe(s) and/or outlet pipe(s) at the point at which they pass through and/or under the wound-facing face of the backing layer to run over the wound bed. These may have a blind bore with perforations, apertures, holes, openings, orifices, slits or slots along the pipes, etc.

These pipes, etc. then effectively form an inlet pipe manifold that delivers the aspirating fluid directly to the wound bed or outlet pipe or collects the fluid directly from the wound respectively. It does so via the holes, openings, orifices, slits or slots in the tubes, pipes, tubules, etc. over most of the wound bed under the backing layer.

It may be desirable that the tubes, pipes or tubules are resiliently flexible, e.g. elastomeric, and preferably soft, structures with good conformability in the wound and the interior of the wound dressing.

When the therapy is applied in this way, the layout of the tubes, pipes, tubules, etc. may depend on the depth and/or capacity of the wound.

Thus, for shallower wounds, examples of suitable forms of such layout of the tubes, pipes, tubules, etc. include ones that consist essentially of one or more of the tubes, etc in a spiral.

A more suitable layout for deeper wounds when the therapy is applied in this way may be one which comprises one or more of the tubes, etc in a helix or spiral helix.

Other suitable layouts for shallower wounds include one which have blind-bore, perforated inlet pipe or outlet pipe manifolds that aspirate fluid in the wound when the dressing is in use.

One or both of these may be such a form, the other may be, e.g. one or more straight blind-bore, perforated radial tubes, pipes or nozzles.

A preferred form of inlet pipe (or less usually outlet pipe) manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound respectively is one that comprise one or more conformable hollow bodies defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure, filled with the irrigant (or less usually aspirate) from the wound, passing through perforations, apertures, holes, openings, orifices, slits or slots in the film, sheet or membrane defining the hollow body or hollow bodies.

These may be of small cross-dimension, so that they may then effectively form microperforations, microapertures or pores in a permeable integer, for example the polymer film, sheet or membrane.

This type of manifold for irrigation (more usually) provides the highest uniformity in the flow distribution of irrigant over the wound at a practical rate to be suitable for use, in particular in chronic wound aspiration and irrigation, and hence to provide a system where materials that are beneficial in promoting wound healing, such as growth factors, cell matrix components, and other physiologically active components of the exudate from a wound, are distributed more evenly under the dressing over the wound bed.

This type of manifold for irrigation (more usually) is noted below with regard to wound fillers under the backing layer, since it is a resiliently flexible, e.g. elastomeric, and soft, structure with good conformability to wound shape. It is urged by its own resilience against the backing layer to apply gentle pressure on the wound bed, and is therefore also capable of acting as a wound filler. The film, sheet or membrane, often has a (generally uniform) thickness similar to that of films or sheets used in conventional wound dressing backing layers.

Another suitable layout is one in which an inlet pipe and/or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound respectively via inlet and/or outlet tubes, pipes or tubules, and the inlet manifold and/or outlet manifold is formed by slots in layers permanently attached to each other in a stack, and the inlet and/or outlet tubes, pipes or tubules are formed by apertures through layers permanently attached to each other in a stack. (In Figure 10a there is shown an exploded isometric view of such a stack, which is non-limiting.)

As also mentioned herein, the backing layer that is applied may be any that is appropriate to the present system of therapy and permits a positive or negative pressure of up to 50% atm., more usually up to 25% atm. to be applied to the wound.

It is thus often a microbe-impermeable film, sheet or membrane, which is substantially flat, depending on any pressure differential on it, and often with a (generally uniform) thickness similar to such films or sheets used in conventional wound dressings, i.e. up to 100 micron, preferably up to 50

micron, more preferably up to 25 micron, and of 10 micron minimum thickness.

The backing layer may often have a rigid and/or resiliently inflexible or stiff area to resist any substantial play between other components that are not mutually integral, and may be stiffened, reinforced or otherwise strengthened, e.g. by a projecting boss.

Such a form of dressing would not be very conformable to the wound bed, and may effectively form a chamber, hollow or cavity defined by a backing layer and the wound bed under the backing layer.

It may be desirable that the interior of the wound dressing conform to the wound bed, even for a wound in a highly exuding state. Accordingly, one form of the dressing is provided with a wound filler under the backing layer.

This is favourably a resiliently flexible, e.g. elastomeric, and preferably soft, structure with good conformability to wound shape. It is urged by its own resilience against the backing layer to apply gentle pressure on the wound bed. The wound filler may be integral with the other components of the dressing, in particular the backing layer. Alternatively, it may be permanently attached to them/it, with an adhesive film, for example, or by heat-sealing, e.g. to a flange or lip extending from the proximal face, so a not to disrupt the relatively fluid-tight seal or closure over the wound that is needed.

Less usually, the wound filler is releasably attached to the backing layer, with an adhesive film, for example, or these components may be a push, snap or twist-lock fit with each other.

The wound filler and the backing layer may be separate structures, permanently unattached to each other.

The wound filler may be or comprise a solid integer, favourably a resiliently flexible, e.g. elastomeric, and preferably soft, structure with good conformability to wound shape.

Examples of suitable forms of such wound fillers are foams formed of a suitable material, e.g. a resilient thermoplastic.

Preferred materials for the fillers include reticulated filtration polyurethane foams with small apertures or pores.

Alternatively or additionally, it may be in the form of, or comprise one or more conformable hollow bodies defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure, filled with a fluid or solid that urges it to the wound shape.

The film, sheet or membrane, often has a (generally uniform) thickness similar to that of films or sheets used in conventional wound dressing backing layers.

That is, up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness, and is often resiliently flexible, e.g. elastomeric, and preferably soft.

Such a filler is often integral with the other components of the dressing, in particular the backing layer, or permanently attached to them/it, with an adhesive film, for example, or by heat-sealing, e.g. to a flange

Examples of suitable fluids contained in the hollow body or bodies defined by a film, sheet or membrane include gases, such as air, nitrogen and argon, more usually air, at a small positive pressure above atmospheric; and liquids, such as water, saline.

Examples also include gels, such as silicone gels, e.g. CaviCare™ gel, or preferably cellulosic gels, for example hydrophilic cross-linked cellulosic gels, such as Intrasite ™ cross-linked materials.

Examples also include aerosol foams, where the gaseous phase of the aerosol system is air or an inert gas, such as nitrogen or argon, more usually air, at a small positive pressure above atmospheric; and solid particulates, such as plastics crumbs.

Of course, if the backing layer is a sufficiently conformable and/or e.g. an upwardly dished sheet, the backing layer may lie under the wound filler, rather than vice versa.

In this type of layout, in order for the wound filler to urge the wound dressing towards the wound bed, it will usually have to be firmly adhered or otherwise releasably attached to the skin around the wound. This is especially the case in those embodiments where the wound filler and the backing layer are separate structures, permanently unattached to each other.

In such a layout for deeper wounds when the therapy is applied in this way, the means for such attachment may also form and maintain a seal or closure over the wound.

Where the filler is over the backing layer, and the fluid inlet pipe(s) and outlet pipe(s) pass through the wound-facing face of the backing layer, they may run through or around the wound filler over the backing layer.

One form of the dressing is provided with a wound filler under the backing layer that is or comprises a resiliently flexible, e.g. elastomeric, and preferably soft, hollow body defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure.

It has apertures, holes, openings, orifices, slits or slots, or tubes, pipes, tubules or nozzles. It communicates with at least one inlet or outlet pipe through at least one aperture, hole, opening, orifice, slit or slot.

The fluid contained in the hollow body may then be the aspirating or irrigating fluid in the apparatus.

The hollow body or each of the hollow bodies then effectively forms an inlet pipe or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound respectively via the holes, openings, orifices, slits or slots, or the tubes, pipes or hoses, etc. in the film, sheet or membrane.

When the therapy is applied in this way, the type of the filler may also be largely determined by the depth and/or capacity of the wound.

Thus, for shallower wounds, examples of suitable wound fillers as a component of a wound dressing include ones that consist essentially of one or more conformable hollow bodies defining an inlet pipe and/or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound.

A more suitable wound filler for deeper wounds when the therapy is applied in this way may be one which comprises one or more conformable hollow bodies defined by, for example a polymer film, sheet or membrane, that at least partly surround(s) a solid integer. This may provide a system with better rigidity for convenient handling.

Unless the wound filler under the backing layer effectively forms an inlet pipe or outlet pipe manifold, in order for aspiration and/or irrigation of the wound bed to occur, it is appropriate for one or more bores, channels, conduits, passages, pipes, tubes, tubules and/or spaces, etc. to run from the point at which the fluid inlet pipe(s) and outlet pipe(s) pass through and/or under the wound-facing face of the backing layer through or around the wound filler under the backing layer.

Less usually, the wound filler is may be open-cell foam with pores that may form such bores, channels, conduits, passages and/or spaces through the wound filler under the backing layer.

Where the filler is or comprises one or more conformable hollow bodies defined by, for example a polymer film, sheet or membrane, it may be provided with means for admitting fluids to the wound bed under the wound dressing.

These may be in the form of pipes, tubes, tubules or nozzles running from the point at which the fluid inlet pipe(s) and outlet pipe(s) pass through and/or under the wound-facing face of the backing layer through or around the wound filler under the backing layer.

All of the suitable layouts for shallower wounds that comprise blind-bore, perforated inlet pipe or outlet pipe manifolds that aspirate fluid in the wound when the dressing is in use, that are described hereinbefore, may be used under a wound filler under the backing layer.

In brief, suitable layouts include ones where one or both manifolds are annular or toroidal (regular, e.g. elliptical or circular or irregular), optionally with blind-bore, perforated radial tubes, pipes or nozzles, branching from the annulus or torus; and/or in a meandering, tortuous, winding, zigzag, serpentine or boustrophedic (i.e. in the manner of a ploughed furrow) pattern, or defined by slots in and apertures through layers attached to each other in a stack.

The inlet and/or outlet tubes, the fluid tube and the fluid supply tube, etc. may be of conventional type, e.g. of elliptical or circular cross-section, and may suitably have a uniform cylindrical bore, channel, conduit or passage throughout their length, and suitably the largest cross-dimension of the bore may be up to 10 mm for large torso wounds, and up to 2 mm for limb wounds.

The tube walls should suitably thick enough to withstand any positive or negative pressure on them. However, the prime purpose of such tubes is to convey fluid irrigant and exudate through the length of the apparatus flow path, rather than to act as pressure vessels. The tube walls may suitably be at least 25 micron thick.

The bore or any perforations, apertures, holes, openings, orifices, slits or slots along the pipes, etc. or in the hollow body or each of the hollow bodies may be of small cross-dimension. They may then effectively form a macroscopic and/or microscopic filter for particulates including cell debris and micro-organisms, whilst allowing proteins and nutrients to pass through.

Such tubes, pipes or hoses, etc. through and/or around the filler, whether the latter is a solid integer and/or one or more resiliently flexible or

conformable hollow bodies, are described in further detail hereinbefore in connection with the inlet pipe(s) and outlet pipe(s).

The whole length of the apparatus for aspirating, irrigating and/or cleansing wounds should be microbe-impermeable once the wound dressing is over the wound in use.

It is desirable that the wound dressing and the interior of the apparatus for aspirating, irrigating and/or cleansing wounds of the present invention is sterile.

The fluid may be sterilised in the fluid reservoir and/or the rest of the system in which the fluid moves by ultraviolet, gamma or electron beam irradiation.

This way, in particular reduces or eliminates contact of internal surfaces and the fluid with any sterilising agent.

Examples of other methods of sterilisation of the fluid also include e.g. the use of:

- ultrafiltration through microapertures or micropores, e.g. of 0.22 to 0.45 micron maximum cross-dimension, to be selectively impermeable to microbes; and
- fluid antiseptics, such as solutions of chemicals, such as chlorhexidine and povidone iodine; metal ion sources, such as silver salts, e.g. silver nitrate; and hydrogen peroxide;

although the latter involve contact of internal surfaces and the fluid with the sterilising agent.

It may be desirable that the interior of the wound dressing, the rest of the system in which the fluid moves, and/or the wound bed, even for a wound in a highly exuding state, are kept sterile after the fluid is sterilised in the fluid reservoir, or that at least naturally occurring microbial growth is inhibited.

Thus, materials that are potentially or actually beneficial in this respect may be added to the irrigant initially, and as desired the amount in increased by continuing addition. Examples of such materials include antibacterial agents (some of which are listed above), and antifungal agents. Amongst those that are suitable are, for example triclosan, iodine, metronidazole, cetrimide, chlorhexidine acetate, sodium undecylenate, chlorhexidine and iodine.

Buffering agents, such as potassium dihydrogen phosphate/ disodium hydrogen phosphate. may be added to adjust the pH, as may local analgesics/anaesthetics, such as lidocaine/lignocaine hydrochloride, xylocaine (adrenoline, lidocaine) and/or anti-inflammatories, to reduce wound pain or inflammation or pain associated with the dressing.

In order to combat the deposition of materials in the flow path from the irrigant, a repellent coating may be used at any point or on any integer in the path in direct contact with the fluid, e.g. on the means for providing simultaneous aspiration and irrigation of the wound or any desired tube or pipe.

Examples of coating materials for surfaces over which the aspirating fluid passes include:

- anticoagulants, such as heparin, and
- high surface tension materials, such as PTFE, and polyamides,

which are useful for growth factors, enzymes and other proteins and derivatives.

The apparatus of the invention for aspirating, irrigating and/or cleansing wounds is provided with means for admitting fluids directly or indirectly to the wound under the wound dressing in the form of a fluid supply tube to a fluid reservoir.

The fluid reservoir for the irrigant may be of any conventional type, e.g. a tube, bag (such as a bag typically used for blood or blood products, e.g. plasma, or for infusion feeds, e.g. of nutrients), chamber, pouch or other structure, e.g. of polymer film, which can contain the irrigant fluid. The

reservoir may be made of a film, sheet or membrane, often with a (generally uniform) thickness similar to that of films or sheets used in conventional wound dressing backing layers, i.e. up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness, and is often a resiliently flexible, e.g. elastomeric, and preferably soft, hollow body.

In all embodiments of the apparatus the type and material of the tubes throughout the apparatus of the invention for aspirating, irrigating and/or cleansing wounds and the fluid reservoir will be largely determined by their function.

To be suitable for use, in particular on chronic timescales, the material should be non-toxic and biocompatible, inert to any active components, as appropriate of the irrigant from the fluid reservoir and/or wound exudate in the apparatus flow path, and, in any use of a two-phase system aspiration and irrigation unit, of the dialysate that moves into the aspirating fluid in the apparatus.

When in contact with irrigant fluid, it should not allow any significant amounts of extractables to diffuse freely out of it in use of the apparatus.

It should be sterilisable by ultraviolet, gamma or electron beam irradiation and/or with fluid antiseptics, such as solutions of chemicals, fluid- and microbe-impermeable once in use, and flexible.

Examples of suitable materials for the fluid reservoir include synthetic polymeric materials, such as polyolefins, such as polyethylene, e.g. high-density polyethylene and polypropylene.
Suitable materials for the present purpose also include copolymers thereof, for example with vinyl acetate and mixtures thereof. Suitable materials for the present purpose further include medical grade poly(vinyl chloride).

Notwithstanding such polymeric materials, the fluid reservoir will often have a stiff area to resist any substantial play between it and components that are not mutually integral, such as the fluid supply tube towards the wound

dressing, and may be stiffened, reinforced or otherwise strengthened, e.g. by a projecting boss.

Materials deleterious to wound healing that are removed using the apparatus include oxidants, such as free radicals, e.g. peroxide and superoxide;
iron II and iron III;
all involved in oxidative stress on the wound bed;
proteases, such as serine proteases, e.g. elastase and thrombin; cysteine proteases; matrix metalloproteases, e.g. collagenase; and carboxyl (acid) proteases;
endotoxins, such as lipopolysaccharides;
autoinducer signalling molecules, such as homoserine lactone derivatives, e.g. oxo-alkyl derivatives;
inhibitors of angiogenesis such as thrombospondin-1 (TSP-1), plasminogen activator inhibitor, or angiostatin (plasminogen fragment);
pro-inflammatory cytokines such as tumour necrosis factor alpha (TNFα) and interleukin 1 beta (IL-1β),
oxidants, such as free radicals, e.g. , e.g. peroxide and superoxide; and
metal ions, e.g. iron II and iron III, all involved in oxidative stress on the wound bed.

It is believed that aspirating wound fluid aids in removal from of the materials deleterious to wound healing from wound exudate and/or irrigant, whilst distributing materials that are beneficial in promoting wound healing in contact with the wound.

A steady state concentration equilibrium of materials beneficial in promoting wound healing may be set up between in the irrigant and/or wound exudate. Aspirating wound fluid aids in the quicker attainment of this equilibrium

Materials beneficial to wound healing that are distributed include cytokines, enzymes, growth factors, cell matrix components, biological signalling molecules and other physiologically active components of the exudate and/or materials in the irrigant that are potentially or actually beneficial in

respect of wound healing, such as nutrients for wound cells to aid proliferation, gases, such as oxygen.

The conduits through which respectively the irrigant and/or wound exudate passes to and from the wound dressing and

i) may have means for modular disconnection and withdrawal of the dressing,

ii) providing an immediate fluid-tight seal or closure over the ends of the conduits and the cooperating tubes in the rest of the apparatus of the invention so exposed,

to prevent continuing passage of irrigant and/or exudate.

The outlet from the means for aspirate flow regulation and/or tubes may be collected and monitored and used to diagnose the status of the wound and/or its exudate.

Any aspirate collection vessel may be of any conventional type, e.g. a tube, bag (such as a bag typically used as an ostomy bag), chamber, pouch or other structure, e.g. of polymer film, which can contain the irrigant fluid that has been bled off. In all embodiments of the apparatus, the type and material of the aspirate collection vessel will be largely determined by its function.

To be suitable for use, the material need only be fluid-impermeable once in use, and flexible.

Examples of suitable materials for the fluid reservoir include synthetic polymeric materials, such as polyolefins, such as poly (vinylidene chloride).

Suitable materials for the present purpose also include polyethylene, e.g. high-density polyethylene, polypropylene, copolymers thereof, for example with vinyl acetate and mixtures thereof.

In a further aspect of the present invention there is provided a conformable wound dressing.

Characterised in that it comprises a backing layer with a wound-facing face which is capable of forming a relatively fluid-tight seal or closure over a wound and has at least one pipe, which passes through and/or under the wound-facing face to allow irrigation and/or aspiration of the wound; the point at which the at least one pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound;
and means for applying flow stress to the wound bed.

The dressing is advantageously provided for use in a bacteria-proof pouch.

Examples of suitable forms of such wound dressings are as described by way of example hereinbefore.

In an aspect of the present invention there is provided a method of treating wounds to promote wound healing using the apparatus for aspirating, irrigating and/or cleansing wounds of the present invention.

The present invention will now be described by way of example only with reference to the accompanying drawings in which:

Figure 1 is a schematic view of an apparatus for aspirating, irrigating and/or cleansing a wound according to the first aspect of the present invention that has a single device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, in combination with means for supply flow regulation, connected to a fluid supply tube, and means for aspirate flow regulation, connected to a fluid offtake tube.

Figure 2 is a schematic view of another apparatus for aspirating, irrigating and/or cleansing a wound according to the first aspect of the present invention that has a first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, with means for aspirate flow regulation, connected to a fluid offtake tube; and a second device for moving fluid through the wound

applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing.

Figures 3 to 7 are cross-sectional views of conformable wound dressings, of the second aspect of the present invention for aspirating and/or irrigating wounds.

In these, Figures 3a to 6a are cross-sectional plan views of the wound dressings, and Figures 3b to 6b are cross-sectional side views of the wound dressings.

Figures 8 to 10 are various views of inlet and outlet manifold layouts for the wound dressings of the second aspect of the present invention for respectively delivering fluid to, and collecting fluid from, the wound.

Figures 11A to D are variants of a two-pump system with essentially identical, and identically numbered, components as in Figure 2, except that there is a pump bypass loop, a filter downstream of the aspirate collection vessel, and a bleed regulator, such as a rotary valve, connected to the fluid offtake tube or to the wound space, for the regulation of the positive or negative pressure applied to the wound.

Figures 12A to C are variants of a two-pump system with essentially identical, and identically numbered, components as in Figures 11, except that they have various means for varying the regulation of the positive or negative pressure applied to the wound.

Figures 13 to 26 are cross-sectional views of conformable wound dressings, of the second aspect of the present invention for aspirating and/or irrigating wounds.

Figure 27a is a plan view and Figure 27b a cross-sectional view of a further conformable wound dressings of the second aspect of the present invention for aspirating and/or irrigating wounds.

Figures 28A and B are variants of a two-pump system with essentially identical, and identically numbered, components as in Figures 11. However, they have alternative means for handling the aspirate flow to the aspirate collection vessel under negative or positive pressure to the wound in simultaneous aspiration and irrigation of the wound, including in Figure 27B a third device for moving fluid into a waste bag.

Figure 29 is a single-pump system essentially with the omission from the apparatus of Figures 11 of the second device for moving irrigant fluid into the wound dressing.

Figure 30 shows a schematic representation of an in vitro method of assessing the effects of flow stress in wound healing. The particular circuit shown is suitable for sequential (fill/empty) irrigation/aspiration or simultaneous irrigation/aspiration.

Referring to Figure 1, the apparatus (1) for aspirating, irrigating and/or cleansing wounds comprises
a conformable wound dressing (2), having
a backing layer (3) which is capable of forming a relatively fluid-tight seal or closure (4) over a wound (5) and
one inlet pipe (6) for connection to a fluid supply tube (7), which passes through the wound-facing face of the backing layer (5) at (8), and
one outlet pipe (9) for connection to a fluid offtake tube (10), which passes through the wound-facing face at (11),
the points (8), (11) at which the inlet pipe and the outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound;
the inlet pipe being connected via means for supply flow regulation, here a valve (14), by the fluid supply tube (7) to a fluid reservoir (12), and
the outlet pipe (9) being connected via means for aspirate flow regulation, here a valve (16) and a fluid offtake tube (10) to waste, e.g. to a collection bag (not shown);
a device for moving fluid through the wound (17), here a diaphragm pump (18), e.g. preferably a small portable diaphragm pump, acting on the fluid aspiration tube (13) to apply a low negative pressure on the wound; and

the valve (14) in the fluid supply tube (7), the valve (16) in the fluid offtake tube (10), and the diaphragm pump (18), providing means for providing simultaneous aspiration and irrigation of the wound (17),
such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (via the means for supply flow regulation) and moved by the device through the flow path.

The operation of the apparatus is as described hereinbefore.

Referring to Figure 2, the apparatus (21) is a variant two-pump system with essentially identical, and identically numbered, components as in Figure 1, except that there is no means for supply flow regulation in the fluid supply tube (7) from the fluid reservoir (12B), and there is a first device for moving fluid through the wound (17), here a diaphragm pump (18A), e.g. preferably a small portable diaphragm pump, acting on the fluid aspiration tube (13) downstream of and away from the wound dressing to apply a low negative pressure on the wound; with means for aspirate flow regulation here a valve (16) connected to the fluid offtake tube (10) and a vacuum vessel (aspirate collection jar) (12A); and a second device for moving fluid through the wound (17), here a peristaltic pump (18B), e.g. preferably a small portable diaphragm pump, applied to the irrigant in the fluid supply tube (7) upstream of and towards the wound dressing, the first device (18A) and second device (18B), and the valve (16) in the fluid offtake tube (10), and the diaphragm pump (18), providing means for providing simultaneous aspiration and irrigation of the wound (17), such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (via the means for supply flow regulation) and moved by the devices through the flow path.

The operation of the apparatus is as described hereinbefore
Referring to Figures 3 to 6, each dressing (41) is in the form of a conformable body defined by a microbe-impermeable film backing layer (42) with a uniform thickness of 25 micron.

It has a wound-facing face (43) which is capable of forming a relatively fluid-tight seal or closure over a wound.

The backing layer (42) extends in use on a wound over the skin around the wound.

On the proximal face of the backing layer (43) on the overlap (44), it bears an adhesive film (45), to attach it to the skin sufficiently to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound-facing face (43) of the wound dressing.

There is one inlet pipe (46) for connection to a fluid supply tube (not shown), which passes through and/or under the wound-facing face (43), and one outlet pipe (47) for connection to a fluid offtake tube (not shown), which passes through and/or under the wound-facing face (43),

Referring to Figures 3a and 3b, one form of the dressing is provided with a wound filler (48) under a circular backing layer (42).

This comprises a generally frustroconical, toroidal conformable hollow body, defined by a membrane (49) which is filled with a fluid, here air or nitrogen, that urges it to the wound shape.

The filler (48) may be permanently attached to the backing layer with an adhesive film (not shown) or by heat-sealing.

The inlet pipe (46) and outlet pipe (47) are mounted centrally in the backing layer (42) above the central tunnel (50) of the toroidal hollow body (48) and each passes through the backing layer (42).

Each extends in pipes (51) and (52) respectively through the tunnel (50) of the toroidal hollow body (48) and then radially in diametrically opposite directions under the body (48).

This form of the dressing is a more suitable layout for deeper wounds.

Referring to Figures 4a and 4b, a more suitable form for shallower wounds is shown.

This comprises a circular backing layer (42) and a circular upwardly dished first membrane (61) with apertures (62) that is permanently attached to the backing layer (42) by heat-sealing to form a circular pouch (63).

The pouch (63) communicates with the inlet pipe (46) through a hole (64), and thus effectively forms an inlet pipe manifold that delivers the aspirating fluid directly to the wound when the dressing is in use.

An annular second membrane (65) with openings (66) is permanently attached to the backing layer (42) by heat-sealing to form an annular chamber (67) with the layer (42).

The chamber (67) communicates with the outlet pipe (47) through an orifice (68), and thus effectively forms an outlet pipe manifold that collects the fluid directly from the wound when the dressing is in use.

Referring to Figures 5a and 5b, a variant of the dressing of Figures 4a and 4b that is a more suitable form for deeper wounds is shown.

This comprises a circular backing layer (42) and a filler (69), in the form of an inverted frustroconical, solid integer, here a resilient elastomeric foam, formed of a thermoplastic, or preferably a cross-linked plastics foam.

It may be permanently attached to the backing layer (42), with an adhesive film (not shown) or by heat-sealing.

A circular upwardly dished sheet (70) lies under and conforms to, but is a separate structure, permanently unattached to, the backing layer (42) and the solid integer (69).

A circular upwardly dished first membrane (71) with apertures (72) is permanently attached to the sheet (70) by heat-sealing to form a circular pouch (73) with the sheet (70).

The pouch (73) communicates with the inlet pipe (46) through a hole (74), and thus effectively forms an inlet pipe manifold that delivers the aspirating fluid directly to the wound when the dressing is in use.

An annular second membrane (75) with openings (76) is permanently attached to the sheet (70) by heat-sealing to form an annular chamber (77) with the sheet (70).

The chamber (77) communicates with the outlet pipe (47) through an orifice (78), and thus effectively forms an outlet pipe manifold that collects the fluid directly from the wound when the dressing is in use.

Alternatively, where appropriate the dressing may be provided in a form in which the circular upwardly dished sheet (70) functions as the backing layer and the solid filler (69) sits on the sheet (70) as the backing layer, rather than under it. The filler (69) is held in place with an adhesive film or tape, instead of the backing layer (42).

Referring to Figures 6a and 6b, a dressing that is a more suitable form for deeper wounds is shown.

This comprises a circular backing layer (42) and a filler (79), in the form of an inverted generally hemispherical integer, permanently attached to the backing layer with an adhesive film (not shown) or by heat-sealing.

Here it is a resilient elastomeric foam or a hollow body filled with a fluid, here a gel that urges it to the wound shape.

The inlet pipe (46) and outlet pipe (47) are mounted peripherally in the backing layer (42).

A circular upwardly dished sheet (80) lies under and conforms to, but is a separate structure, permanently unattached to, the backing layer (42) and the filler (79).

A circular upwardly dished bilaminate membrane (81) has a closed channel (82) between its laminar components, with perforations (83) along its length on the outer surface (84) of the dish formed by the membrane (81) and an opening (85) at the outer end of its spiral helix, through which the channel (82) communicates with the inlet pipe (46), and thus effectively forms an inlet pipe manifold that delivers the aspirating fluid directly to the wound when the dressing is in use.

The membrane (81) also has apertures (86) between and along the length of the turns of the channel (82).

The inner surface (87) of the dish formed by the membrane (81) is permanently attached at its innermost points (88) with an adhesive film (not shown) or by heat-sealing to the sheet (80). This defines a mating closed spirohelical conduit (89).

At the outermost end of its spiral helix, the conduit (89) communicates through an opening (90) with the outlet pipe (47) and is thus effectively an outlet manifold to collect the fluid directly from the wound via the apertures (86).

Referring to Figures 7a and 7b, one form of the dressing is provided with a circular backing layer (42).

A first (larger) inverted hemispherical membrane (92) is permanently attached centrally to the layer (42) by heat-sealing to form a hemispherical chamber (94) with the layer (42).

A second (smaller) concentric hemispherical membrane (93) within the first is permanently attached to the layer (42) by heat-sealing to form a hemispherical pouch (95).

The pouch (95) communicates with the inlet pipe (46) and is thus effectively an inlet manifold, from which pipes (97) radiate hemispherically and run to the wound bed to end in apertures (98). The pipes (97) deliver the aspirating fluid directly to the wound bed via the apertures (98).

The chamber (94) communicates with the outlet pipe (47) and is thus effectively an outlet manifold from which tubules (99) radiate hemispherically and run to the wound bed to end in openings (100). The tubules (99) collect the fluid directly from the wound via the openings (100).

Referring to Figures 8a to 8d, one form of the dressing is provided with a square backing layer (42) and first tube (101) extending from the inlet pipe (46), and second tube (102) extending from the outlet pipe (47) at the points at which they pass through the backing layer, to run over the wound bed.

These pipes (101), (102) have a blind bore with orifices (103), (104) along the pipes (101), (102).

These pipes (101), (102) respectively form an inlet pipe or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound respectively via the orifices.

In Figures 8a and 8d, one layout of each of the pipes (101), (102) as inlet pipe and outlet pipe manifolds is a spiral.

In Figure 8b, the layout is a variant of that of Figures 8a and 8b, with the layout of the inlet manifold (101) being a full or partial torus, and the outlet manifold (102) being a radial pipe.

Referring to Figure 8c, there is shown another suitable layout in which the inlet manifold (101) and the outlet manifold (102) run alongside each other over the wound bed in a boustrophedic pattern, i.e. in the manner of ploughed furrows.

Referring to Figures 9a to 9d, there are shown other suitable layouts for deeper wounds, which are the same as shown in Figures 8a to 8d. The square backing layer (42) however has a wound filler (110) under, and may be permanently attached to, the backing layer (42), with an adhesive film (not shown) or by heat-sealing, which is an inverted hemispherical solid

integer, here a resilient elastomeric foam, formed of a thermoplastic, preferably a cross-linked plastics foam.

Under the latter is a circular upwardly dished sheet (111) which conforms to, but is a separate structure, permanently unattached to, the solid filler (110). Through the sheet (111) pass the inlet pipe (46) and the outlet pipe (47), to run over the wound bed. These pipes (101), (102) again have a blind bore with orifices (103), (104) along the pipes (101), (102).

Alternatively (as in Figures 5a and 5b), where appropriate the dressing may be provided in a form in which the circular upwardly dished sheet (111) functions as the backing layer and the solid filler (110) sits on the sheet (42) as the backing layer, rather than under it. The filler (110) is held in place with an adhesive film or tape, instead of the backing layer (42).

In Figures 10a to 10c, inlet and outlet manifolds for the wound dressings for respectively delivering fluid to, and collecting fluid from, the wound, are formed by slots in and apertures through layers permanently attached to each other in a stack.

Thus, in Figure 10a there is shown an exploded isometric view of an inlet manifold and outlet manifold stack (120) of five square coterminous thermoplastic polymer layers, being first to fifth layers (121) to (125), each attached with an adhesive film (not shown) or by heat-sealing to the adjacent layer in the stack (120).

The topmost (first) layer (121) (which is the most distal in the dressing in use) is a blank square capping layer.

The next (second) layer (122), shown in Figure 10b out of the manifold stack (120), is a square layer, with an inlet manifold slot (126) through it.

The slot (126) runs to one edge (127) of the layer (122) for connection to a mating end of a fluid inlet tube ((not shown), and spreads into four adjacent branches (128) in a parallel array with spaces therebetween.

The next (third) layer (123) is another square layer, with inlet manifold apertures (129) through the layer (123) in an array such that the apertures (129) are in register with the inlet manifold slot (126) through the second layer (122) (shown in Figure 10b).

The next (fourth) layer (124), shown in Figure 10c out of the manifold stack (120), is another square layer, with inlet manifold apertures (130) through the layer (124) in an array such that the apertures (130) are in register with the apertures (129) through the third layer (123). It also has an outlet manifold slot (131) through it.

The slot (131) runs to one edge (132) of the layer (124) on the opposite side of the manifold stack (120) from the edge (127) of the layer (122), for connection to a mating end of a fluid outlet tube (not shown).

It spreads into three adjacent branches (133) in a parallel array in the spaces between the apertures (130) in the layer (124) and in register with the spaces between the apertures (129) in the layer (122).

The final (fifth) layer (125) is another square layer, with inlet manifold apertures (134) through the layer (125) in an array such that the apertures (134) are in register with the inlet manifold apertures (130) through the fourth layer (124) (in turn in register with the apertures (129) through the third layer (123). It also has outlet manifold apertures (135) in the layer (125) in an array such that the apertures (135) are in register with the outlet manifold slot (131) in the fourth layer (124).

It will be seen that, when the layers (121) to (125) are attached together to form the stack (120), the topmost (first) layer (121), the inlet manifold slot (126) through the second layer (122), and the third layer (123) cooperate to form an inlet manifold in the second layer (122), which is in use is connected to a mating end of a fluid inlet tube (not shown).

The inlet manifold slot (126) through the second layer (122), and the inlet manifold apertures (129), (130) and (134) through the layers (123), (124) and (125), all being mutually in register, cooperate to form inlet manifold conduits though the third to fifth layers (123), (124) and (125) between the

inlet manifold in the second layer (122) and the proximal face (136) of the stack (120).

The third layer (121), the outlet manifold slot (131) through the fourth layer (124), and the fifth layer (125) cooperate to form an outlet manifold in the fourth layer (124), which is in use is connected to a mating end of a fluid outlet tube (not shown).

The outlet manifold slot (131) through the fourth layer (124), and the outlet manifold apertures (135) through the fifth layer (125), being mutually in register, cooperate to form outlet manifold conduits though the fifth layer (125) between the outlet manifold in the fourth layer (124) and the proximal face (136) of the stack (120).

Referring to Figure 11A, the apparatus (21) is a variant two-pump system with essentially identical, and identically numbered, components as in Figure 2.

Thus, there is
a means for supply flow regulation, here a valve (14) in the fluid supply tube (7) from the fluid reservoir (12B), and
a first device for moving fluid through the wound (17), here a fixed-speed diaphragm pump (18A), e.g. preferably a small portable diaphragm pump, acting not on the fluid aspiration tube (13), but on an air aspiration tube (113) downstream of and away from an aspirate collection vessel (12A) to apply a low negative pressure on the wound through the aspirate collection vessel (12A); with
a second device for moving fluid through the wound (17), here a fixed-speed peristaltic pump (18B), e.g. preferably a small portable peristaltic pump, applied to the irrigant in the fluid supply tube (7) upstream of and towards the wound dressing,
the first device (18A) and second device (18B), and the valve (14) in the fluid supply tube (7), providing means for providing simultaneous aspiration and irrigation of the wound (17), such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (via the means for supply flow regulation) and moved by the devices through the flow path.

There is no means for aspirate flow regulation, e.g. a valve connected to the fluid offtake tube (10).

Since first device (18A) and second device (18B) are fixed-speed, the valve (14) in the fluid supply tube (7) provides the sole means for varying the irrigant flow rate and the low negative pressure on the wound.
The following extra features are present :

The second device, the fixed-speed peristaltic pump (18B), is provided with means for avoiding over-pressure, in the form of a bypass loop with a non-return valve (115). The loop runs from the fluid supply tube (7) downstream of the pump (18B) to a point in the fluid supply tube (7) upstream of the pump (18B).

A pressure monitor (116) connected to the fluid offtake tube (10) has a feedback connection to a bleed regulator, here a motorised rotary valve (117) on a bleed tube (118) running to and centrally penetrating the top of the aspirate collection vessel (12A). This provides means for holding the low negative pressure on the wound at a steady level.

A filter (119) downstream of the aspirate collection vessel (12A) prevents passage of gas- (often air-) borne particulates, including liquids and micro-organisms, from the irrigant and/or exudate that passes into the aspirate collection vessel (12A) into the first device (18A), whilst allowing the carrier gas to pass through the air aspiration tube (113) downstream of it to the first device (18A). The operation of the apparatus is as described hereinbefore

Referring to Figure 11B, this shows an alternative layout of the essentially identical, and identically numbered, components in Figure 11A downstream of point A in Figure 11A. The bleed tube (118) runs to the air aspiration tube (113) downstream of the filter (119), rather than into the aspirate collection vessel (12A). This provides means for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore

Referring to Figure 11C, this shows an alternative layout of the essentially identical, and identically numbered, components in Figure 11A upstream of point B in Figure 11A. The second device (18B) is a variable-speed pump, and the valve (14) in the fluid supply tube (7) is omitted.

The second device (18B) is the sole means for varying the irrigant flow rate and the low negative pressure on the wound. The operation of the apparatus is as described hereinbefore

Referring to Figure 11D, this shows an alternative layout of the essentially identical, and identically numbered, components in Figure 11A downstream of point B in Figure 11A.

The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to the bleed regulator, motorised rotary valve (117) on a bleed tube (118) running to the monitor offtake tube (120). This provides means for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore

Referring to Figure 12A, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 11A downstream of point B in Figure 11A.

The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to a means for aspirate flow regulation, here a motorised valve (16) in the air aspiration tube (113) downstream of the filter (119).

This provides means for aspirate flow regulation and for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore

Referring to Figure 12B, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 12A downstream of point B in Figure 11A. The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to

a means for aspirate flow regulation, here a motorised valve (16), in the fluid offtake tube (10) upstream of the aspirate collection vessel (12A).

This provides means for aspirate flow regulation and for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore

Referring to Figure 12C, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 12A downstream of point B in Figure 11A. The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to a variable-speed first device (18A), here a variable-speed pump, downstream of the filter (119), and the valve (16) in the fluid offtake tube (10) is omitted.

This provides means for aspirate flow regulation and for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore.

Referring to Figures 13 to 15, these forms of the dressing are provided with a wound filler (348) under a circular backing layer (342).

This comprises respectively a generally downwardly domed or toroidal, or oblately spheroidal conformable hollow body, defined by a membrane (349) which is filled with a fluid, here air or nitrogen, that urges it to the wound shape.

The filler (348) is permanently attached to the backing layer via a boss (351), which is e.g. heat-sealed to the backing layer (342).

An inflation inlet pipe (350), inlet pipe (346) and outlet pipe (347) are mounted centrally in the boss (351) in the backing layer (342) above the hollow body (348). The inflation inlet pipe (350) communicates with the interior of the hollow body (348), to permit inflation of the body (348).

The inlet pipe (346) extends in a pipe (352) effectively through the hollow body (348). The outlet pipe (347) extends radially immediately under the backing layer (342).

In Figure 13, the pipe (352) communicates with an inlet manifold (353), formed by a membrane (361) with apertures (362) that is permanently attached to the filler (348) by heat-sealing.

It is filled with foam (363) formed of a suitable material, e.g. a resilient thermoplastic. Preferred materials include reticulated filtration polyurethane foams with small apertures or pores.

In Figure 14, the outlet pipe (347) communicates with a layer of foam (364) formed of a suitable material, e.g. a resilient thermoplastic. Again, preferred materials include reticulated filtration polyurethane foams with small apertures or pores.

In all of Figures 13, 14 and 15, in use, the pipe (346) ends in one or more openings that deliver the irrigant fluid directly from the wound bed over an extended area.

Similarly, the outlet pipe (347) effectively collects the fluid radially from the wound periphery when the dressing is in use.

Referring to Figure 16, the dressing is also provided with a wound filler (348) under a circular backing layer (342).

This also comprises a generally toroidal conformable hollow body, defined by a membrane (349) which is filled with a fluid, here air or nitrogen, that urges it to the wound shape.

The filler (348) may be permanently attached to the backing layer (342) via a first boss (351) and a layer of foam (364) formed of a suitable material, e.g. a resilient thermoplastic. Again, preferred materials include reticulated filtration polyurethane foams with small apertures or pores.

The first boss (351) and foam layer (364) are respectively heat-sealed to the backing layer (342) and the boss (351).

An inflation inlet pipe (350), inlet pipe (346) and outlet pipe (347) are mounted centrally in the first boss (351) in the backing layer (342) above the toroidal hollow body (348).

The inflation inlet pipe (350), inlet pipe (346) and outlet pipe (347) respectively each extend in a pipe (353), (354) and (355) through a central tunnel (356) in the hollow body (348) to a second boss (357) attached to the toroidal hollow body (348).

The pipe (353) communicates with the interior of the hollow body (348), to permit inflation of the body (348).

The pipe (354) extends radially through the second boss (357) to communicate with an inlet manifold (352), formed by a membrane (361).

This is permanently attached to the filler (348) by heat-sealing in the form of a reticulated honeycomb with openings (362) that deliver the irrigant fluid directly to the wound bed over an extended area.

The pipe (355) collects the fluid flowing radially from the wound centre when the dressing is in use.
This form of the dressing is a more suitable layout for deeper wounds

In Figure 17, the dressing is similar to that of Figure 16, except that the toroidal conformable hollow body, defined by a membrane (349), is filled with a fluid, here a solid particulates, such as plastics crumbs or beads, rather than a gas, such as air or an inert gas, such as nitrogen or argon. The inflation inlet pipe (350) and pipe (353) are omitted from the central tunnel (356).

Examples of contents for the body (348) also include gels, such as silicone gels or preferably cellulosic gels, for example hydrophilic cross-linked

cellulosic gels, such as Intrasite ™ cross-linked materials. Examples also include aerosol foams, and set aerosol foams, e.g. CaviCare™ foam.

Referring to Figures 18 and 19, another form for deeper wounds is shown. This comprises a circular backing layer (342) and a lobed chamber (363) in the form of a deeply indented disc much like a multiple Maltese cross or a stylised rose.

This is defined by an upper impervious membrane (361) and a lower porous film (362) with apertures (364) that deliver the irrigant fluid directly from the wound bed over an extended area.

A number of configurations of the chamber (363) are shown, all of which are able to conform well to the wound bed by the arms closing in and possibly overlapping in insertion into the wound.

In a particular design of the chamber (363), shown lowermost, on of the arms extended and provided with an inlet port at the end of the extended arm. This provides the opportunity for coupling and decoupling the irrigant supply remote from the dressing and the wound in use.

An inlet pipe (346) and outlet pipe (347) are mounted centrally in a boss (351) in the backing layer (342) above the chamber (363). The inlet pipe (346) is permanently attached to, and communicate with the interior of, the chamber (363), which thus effectively forms an inlet manifold. The space above the chamber (363) is filled with a loose gauze packing (364). .

In Figure 18, the outlet pipe (347) collects the fluid from the interior of the dressing from just under the wound-facing face (343) of the backing layer (342).

A variant of the dressing of Figure 18 is shown in Figure 19. The outlet pipe (347) is mounted to open at the lowest point of the space above the chamber (363) into a piece of foam (374).

In Figure 20, the dressing is similar to that of Figure 13, except that the inlet pipe (352) communicates with an inlet manifold (353), formed by a

membrane (361) with apertures (362), over the upper surface of the generally downwardly domed wound hollow filler (348), rather than through it.

In Figure 21, the dressing is similar to that of Figure 14, with the addition of an inlet manifold (353), formed by a membrane (361) with apertures (362), over the lower surface of the generally downwardly domed annular wound hollow filler.

In Figure 22, the generally downwardly domed annular wound hollow filler is omitted.

Referring to Figure 23, another form for deeper wounds is shown. An inlet pipe (346) and outlet pipe (347) are mounted centrally in a boss (351) in the backing layer (342) above a sealed-off foam filler (348).

The inlet pipe (346) is permanently attached to and passes through the filler (348) to the wound bed. The outlet pipe (347) is attached to and communicates with the interior of, a chamber (363) defined by a porous foam attached to the upper periphery of the filler (348). The chamber (363) thus effectively forms an outlet manifold.

In Figure 24, the foam filler (348) is only partially sealed-off. The inlet pipe (346) is permanently attached to and passes through the filler (348) to the wound bed.
The outlet pipe (347) is attached to and communicates with the interior of the foam of the filler (348). Fluid passes into an annular gap (349) near the upper periphery of the filler (348) into the foam, which thus effectively forms an outlet manifold.

Figures 25 and 26 show dressings in which the inlet pipe (346) and outlet pipe (347) pass through the backing layer (342).

In Figure 25, they communicate with the interior of a porous bag filler (348) defined by a porous film (369) and filled with elastically resilient plastics bead or crumb.

In Figure 26, they communicate with the wound space just below a foam filler (348). The foam (348) may CaviCare ™ foam, injected and formed in situ around the pipes (346) and (347).

Referring to Figure 27, another form for deeper wounds is shown. This comprises a circular, or more usually square or rectangular backing layer (342) and a chamber (363) in the form of a deeply indented disc much like a multiple Maltese cross or a stylised rose.

This is defined by an upper impervious membrane (361) and a lower porous film (362) with apertures (364) that deliver the irrigant fluid directly to the wound bed over an extended area, and thus effectively forms an inlet manifold. Three configurations of the chamber (363) are shown in Figure 27b, all of which are able to conform well to the wound bed by the arms closing in and possibly overlapping in insertion into the wound.

The space above the chamber (363) is filled with a wound filler (348) under the backing layer (342). This comprises an oblately spheroidal conformable hollow body, defined by a membrane (349) that is filled with a fluid, here air or nitrogen, that urges it to the wound shape.

A moulded hat-shaped boss (351) is mounted centrally on the upper impervious membrane (361) of the chamber (363). It has three internal channels, conduits or passages through it (not shown), each with entry and exit apertures. The filler (348) is attached to the membrane (361) of the chamber (363) by adhesive, heat welding or a mechanical fixator, such as a cooperating pin and socket.

An inflation inlet pipe (350), inlet pipe (346) and outlet pipe (347) pass under the edge of the proximal face of the backing layer (342) of the dressing.

It extend radially immediately under the filler (348) and over the membrane (361) of the chamber (363) to each mate with an entry aperture in the boss (351).

An exit to the internal channel, conduit or passage through it that receives the inflation inlet pipe (350) communicates with the interior of the hollow filler (348), to permit inflation.

An exit to the internal channel, conduit or passage that receives the inlet pipe (346) communicates with the interior of the chamber (363) to deliver the irrigant fluid via the chamber (363) to the wound bed over an extended area.

Similarly, an exit to the internal channel, conduit or passage that receives the outlet pipe (347) communicates with the space above the chamber (363) and under the wound filler (348), and collects flow of irrigant and/or wound exudate radially from the wound periphery.

Referring to Figure 28A, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 12C downstream of point B in Figure 12A, and alternative means for handling the aspirate flow to the aspirate collection vessel under negative or positive pressure to the wound.

The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to a variable-speed first device (18A), here a variable-speed pump, upstream of the aspirate collection vessel (12A), and the filter (119) and the air aspiration tube (113) are omitted. This provides means for aspirate flow regulation and for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore.

Referring to Figure 28B, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 12C downstream of point B in Figure 11A, and alternative means for handling the aspirate flow to the aspirate collection vessel under negative or positive pressure to the wound. The pressure monitor (116) is omitted, as is the feedback connection to a variable-speed first device (18A), here a variable-speed pump, downstream of the aspirate collection vessel (12A) and the filter (119). A third device (18C), here a fixed-speed pump, provides means

for moving fluid from the aspirate collection vessel (12A) into a waste bag (12C). The operation of the apparatus is as described hereinbefore.

Referring to Figure 29, this shows an alternative layout of the essentially identical, and identically numbered, components in Figure 11A upstream of point A in Figure 11A.

It is a single-pump system essentially with the omission from the apparatus of Figure 11A of the second device for moving irrigant fluid into the wound dressing. The operation of the apparatus is as described hereinbefore.

Referring to Figure 30, a suitable apparatus for assessing the effect of flow stress on cells in a simulated wound is shown.

A pump (18b) pumps irrigation fluid from a reservoir (12) through a 3 way valve (14) which can be configured to allow normal continuous flow, emptying of the test chamber (400) under vacuum, or emptying of the test chamber (400) at atmospheric pressure.

The irrigation fluid passes into a test chamber (400) described in more detail later. The aspirate leaving the test chamber (400) passes into a waste reservoir (19).

A source of vacuum (18a) manifolds the system at a vacuum (950 mbar) and draws the aspirate into the waste reservoir (19). An additional pump (401) recycles the aspirate from the waste reservoir (19) back to the irrigant reservoir (12). This is suitable for an in vitro system, but would generally be unsuitable for treatment of a patient where the aspirate would contain quantities of deleterious compounds. In such cases a system wherein the vacuum (401) is used would be suitable as the waste aspirant is not recycled.

In vitro example demonstrating the efficacy of the Flow Stress in stimulating cell activity in a wound model.

An apparatus of the present invention was constructed essentially as in Figure 30.

The circuit has the means for fluid cleansing of a wound using an apparatus where an irrigant or fluid of some nature is delivered continually to the wound bed and the resultant wound exudate/fluid mixture is at the same time continually aspirated from the wound and is pumped to waste (i.e. simultaneous aspiration/irrigation – SIA). The cell chamber (400) representing the wound bed is held under vacuum to simulate negative pressure (pressure range <10% atmospheric). (For the experiments the aspirant was not pumped to waste but was re-circulated). The circuit was also used to provide a system where the wound is subjected to repeated iteration of a cycle of fluid delivery followed by a period of aspiration under reduced pressure (i.e. sequential irrigation/aspiration – SEQ).

The apparatus comprised a surrogate wound chamber (400) (Minucells perfusion chamber) in which normal diploid human fibroblasts were cultured on 13 mm diameter (Thermanox polymer) cover slips retained in a two part support (Minnucell Minusheets). Tissues present in the healing wound that must survive and proliferate were represented by the cells within the chamber. Nutrient medium (DMEM with 5% FCS with 1% Buffer All) to simulate an irrigant fluid/wound exudate mixture was pumped from a reservoir into the base of chamber where it bathed the fibroblasts and was removed from the top of the chamber and returned to a second reservoir. The wound chamber was maintained at less than atmospheric pressure by means of a Vacuum pump (18A) in line with the circuit. An air bleed fluid control valve was additionally positioned in the circuit so that on opening the air bleed for a time and closing the fluid flow, the simulated irrigant fluid/wound exudate mixture was evacuated from the chamber and the fibroblasts were maintained in a moist environment under a negative pressure relative to the atmosphere.

The pumps for the circuit were peristaltic pumps acting on silicone (or equivalent) elastic tubing. The circuit was exposed to a vacuum of no more than 10% atmospheric pressure, (with a range of 950 mbar to 1044 mbar). The internal diameter of the tubing was 1.0 mm. A total volume for the

circuit including the chamber and the reservoir was between 50 and 220 ml. The flow rates used were at 0.1 ml min^{-1}

Circuit comprised of an upstream of the wound chamber, a heat exchanger such that the temperature of the nutrient media bathing the cells reaches between 35 °C and 37 °C.

Experiments were conducted that simulated conditions not uncommon for healing wounds whereby the nutrient media delivered to the wound site was supplemented by microstress (the term microstress is used in this example to relate to flow stress) provided by increasing the rate of media flow over the cells to 1.4 ml min^{-1} for 6 hours.

An experiment was conducted that simulated conditions that are not uncommon for healing wounds whereby a fluid was delivered to the wound bed and the application of a vacuum is used to remove the mixture of fluid and exudate to a waste reservoir whereby an air bleed fluid control valve was additionally positioned in the circuit so that on opening the air bleed occurred for a time and closed the fluid flow, the simulated irrigant fluid/wound exudate mixture was evacuated from the chamber and the fibroblasts were maintained under a negative pressure relative to the atmosphere. This represents an empty / fill system, 10 cycles of empty/ fill were performed with each fill or empty phase lasting 1 hour.

Circuit apparatus were constructed essentially as in Figure 2 above and consisted of:

A) a control system which contained:
   1.empty/fill system with 10 x cycles of 1 hour empty/ 1 hour fill over a total of 48 hours and
   2.the chambers representing the wound bed were exposed to microstress; or
   3. The chambers representing the wound bed were NOT exposed to microstress.

B) The test apparatus:
   1.a continuous flow system over a total of 48 hours and

2.the chambers representing the wound bed were exposed to microstress; or

3. the chambers representing the wound bed were NOT stimulated by microstress treatment

Method in More Detail

Cells

Human dermal fibroblasts (HS8/BS04) grown at 37°C/5% CO_2, in T175 flasks containing 35 ml DMEM /10% FCS media were washed in PBS and lifted using 1 x trypsin/EDTA (37°C for 5 min). Trypsin inhibition was achieved by adding 10 ml DMEM/10% FCS media and the cells pelleted by centrifugation (Hereus Megafuge 1.0R; 1000 rpm for 5 min). The media was discarded and cells re-suspended in 10 ml DMEM/10% FCS. Cells were counted using a haemocytometer and diluted in DMEM/10% FCS to obtain 100,000 cells per ml.

Cells (100 µl of diluted stock) were transferred to each 13mm Thermanox tissue culture coated cover slip (cat. 174950, lot 591430) in a 24 well plate and incubated for 1 hr at 37°C/5% CO_2 to allow cell adherence. After 1 h, 1 ml DMEM/10% FCS media was added per well and the cells incubated overnight in the above conditions.

Following overnight incubation, cells were assessed visually for growth under the microscope and those with growth were inserted into cover slip holders (Vertriebs-Gmbh, cat no. 1300) for assembly in the Minucell chamber (Vertriebs-Gmbh, Cat no. 1301).

Media

Cells were grown in DMEM media (Sigma, no. D6429) supplemented with 10 % foetal calf serum; l-glutamine, non-essential amino acids and penicillin/streptomycin (various lot numbers). Media used in the experimental systems was buffered with Buffer-All media (Sigma, lot 75K2325) to ensure stable pH of the media.

Minucell Flow systems

Systems (4) were made up as follows:

- SIA (simultaneous irrigate aspirate) only
- SEQ (sequential irrigate aspirate) only
- SIA plus microstress
- SEQ plus microstress

Media (50 ml) was transferred to each reservoir bottle. The Minucell chambers were filled with 4 ml media and 6 coverslips inserted. The systems were set-up as shown in figure 30 (the pumps were set to run at 0.1 ml/min); hot plates set to 45°C; Discofix 3-way valves (Arnolds lot 04A2092042 c/z); vacuum pump (Ilmvac VCZ 324, asset no 6481, set to 950 mbar).

Media was circulated at 0.1ml/min continuously. In empty/fill systems, the Minucell chambers were emptied by stopping the media flow and switching the 3-way valve to allow air through an attached 0.22 μm filter. When fully emptied, the 3-way valve was closed between the valve and the pump and kept under vacuum. Elevation of the 3-way valve ensured media did not pass through the 0.22 μm filter by gravity flow. After 1 h, the 3-way valve was switched back to the starting position to allow the Minucell chamber to fill and flow rate returned to 0.1ml/min. Continuous irrigate/aspirate systems were run continuously under vacuum at 0.1ml/min for 48 h.

The vacuum pump was set to 950 mbar. The atmospheric pressure varied daily, up to a maximum value of 1044 mbar; therefore the difference in pressure between the systems and the atmosphere was always under 10 %. The fill/empty systems were treated as per Table 1.

Microstress (i.e. Flow Stress)

Microstress stimulation was provided by increasing the flow rate of the media in the system to 1.4 ml/min for the first 6 hours of the experiment. The flow rate was then returned to 0.1 ml/min

Table 1. Fill/empty regime for Minucell chambers.

Day 1 – 4 x empty/fill cycles
Day 2 – 4 x empty fill cycles
Day 3 – 2 x empty/fill cycles and WST assay

WST Assay

A WST assay to measure the cells mitochondrial activity was performed on 6 coverslips from each system. WST reagent (Roche, lot 102452000) was diluted to 10% v/v in DMEM/5% FCS/buffer all media. The coverslips were removed from the Minucell chamber and washed in 1 ml PBS. PBS was removed and 200 µl WST/DMEM media added. The coverslips were then incubated at 37°C for 45 min before transferring 150 µl to a 96 well plate. The absorbance at 450 nm with reference at 655 nm was determined using Ascent Multiskan Microtitre plate reader.

Results and Conclusions

The following results were obtained for a circuit comprising a wound chamber as above containing a total volume of nutrient media (104 ml) pumped at a flow rate of 0.1 ml min^{-1} and where vacuum was set at 950 mbar and where atmospheric pressure varied up to a maximum value of 1044 mbar. The wound chamber and media were held at 37°C for 48 hours and exposed to microstress. In one set of wound chambers continuous flow was maintained. In a second set of chambers 10 cycles of empty/ fill were performed with each fill or empty phase lasting 1 hour.

In samples where either

a) empty/fill system with 10 x cycles of 1 hour empty/ 1 hour fill over a total of 48 hours
b) the exposure to microstress is omitted,

the survival and growth of the fibroblasts is generally relatively poor.

However, when the nutrient medium flow in the first circuit is

a) is delivered continually to the Minucell chamber and the resultant nutrient medium is at the same time continually aspirated from the Minucell chamber under vacuum, and

b) is exposed to microstress

the fibroblasts survive and proliferate to a far greater extent during a 48 hour period than the control empty/fill circuits.

The results are shown in Table 2.

Table 2

Conditions	Mean of cell activity* after 48 hours. N=2
Continuous flow (SIA) flow	0.54
Continuous flow (SIA) plus)microstress	0.61
Fill/empty 10 cycles	0.28
Fill empty 10 cycles plus microstress	0.51

*Cell activity measured with a WST (Tetrazolium based mitochondrial dehdrogenase activity assay).

The combination of microstress and continuous fluid flow at 0.1 ml min^{-1} with waste fluid removal under vacuum of no more than 10% atmostpheric pressure, (950 mbar and atmospheric pressure varied up to a maximum value of 1044 mbar) resulted in an improvement in the healing response of the cells. In the fill empty cycle system the improvement was even more pronounced, resulting in an almost doubling of cell activity.

These results suggest that application of microstress (i.e. flow stress) to a wound in both simultaneous and sequential irrigate/aspirate systems may be of significant benefit to wound healing.

CLAIMS

1) An apparatus for aspirating, irrigating and/or cleansing a wound, comprising:

a) a fluid flow path, comprising a conformable wound dressing, having a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound,

at least one pipe which passes through and/or under the wound-facing face to allow irrigation and/or aspiration of the wound,

wherein the point at which the at least one pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound, when in use;

b) a fluid reservoir connectable by a fluid supply tube to the at l east one pipe and;

c) at least one device for moving fluid through the wound dressing to the wound and/or moving fluid from the wound;

characterised in that the apparatus comprises

d) means for applying flow stress to the wound bed.

2) The apparatus of claim 1 which comprises at least one inlet pipe for connection to a fluid supply tube to allow irrigation and at least one outlet pipe for connection to a fluid offtake tube to allow aspiration, each of which passes through and/or under the wound-facing face.

3) The apparatus of claim 2 which comprises means for simultaneous aspiration and irrigation of the wound, such that irrigant fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube while aspirate fluid is aspirated by a device through the fluid offtake.

4) The apparatus of any preceding claim wherein the means for applying flow stress to the wound bed include means for applying, controlling and/or varying fluid flow under the wound dressing.

5) The apparatus of any preceding claim wherein the means for applying flow stress to the wound bed comprises means to impose:

a) a linear flow of irrigant across the wound bed,

b) a relatively high rate of irrigant flow across the wound bed, or
c) a combination of the two.

6) The apparatus of any preceding claim wherein the means for applying flow stress to the wound bed comprises means to impose relatively high flow rates or velocities of fluid flow under the wound dressing, changes in the flow rates or velocities of fluid flow under the wound dressing, or changes in direction of flow of fluid from positive to negative over the wound bed.

7) The apparatus of any preceding claim wherein the device for moving fluid through the wound provides, at least in part, the means for applying flow stress to the wound bed.

8) The apparatus of any proceding claim wherein the device for moving fluid through the wound is a diaphragm pump or peristaltic pump.

9) The apparatus of claim any preceding claim wherein the means for applying flow stress to the wound bed comprises means to impose a constant flow of fluid at a desired flow rate.

10) The apparatus of claim any preceding claim wherein the means for applying flow stress to the wound bed comprises means to impose a relatively high pressure drop between the interior of an inlet manifolds comprised in the dressing and the wound bed.

11) The apparatus of any preceding claim wherein the means for applying flow stress to the wound bed comprises means to impose a varied flow rate of constant direction.

12) The apparatus of claim 11 wherein the varied flow rate is either randomly or regularly cyclical.

13) The apparatus of claim 12 wherein the regular or random cycles of flow rate have a frequency of up to 48 per 24 hours.

14) The apparatus of any one of claims 11 to 13 wherein the means for applying flow stress to the wound bed is capable of regularly or randomly pulsing a flow rate of fluid.

15) The apparatus of claim 14 wherein the pulses of flow velocity have a frequency of from 1 to 60 per min.

16) The apparatus of any one of claims 11 to 15 wherein the means for applying flow stress to the wound bed is capable of varying flow rate in a random or regular cycle and regularly or randomly pulsing a flow rate of fluid.

17) The apparatus of any preceding claim wherein the means for applying flow stress to the wound bed comprises means to impose fluid flow at a linear velocity of up to 0.03 m/s in a 100 micrometre gap or channel between wound bed and dressing.

18) The apparatus of any preceding claim wherein the means for applying flow stress to the wound bed comprises means to creating a shear stress on the wound bed of the order of from 12 to 13 dynes/cm^2.

19) The apparatus of any preceding claim wherein the means for applying flow stress to the wound bed comprises means to impose a flow rate of from 70 to 200ml/hr.

20) The apparatus of any preceding claim wherein the means for applying flow stress to the wound bed includes features in the conformation of the wound dressing.

21) The apparatus of claim 20 wherein the features in the conformation are on the wound-facing face of the dressing.

22) The apparatus of any preceding claim wherein the means for applying flow stress to the wound bed comprises one or more

modules capable of imposing linear flow of the irrigant across the wound bed at any appropriate point for flow stressing the wound.

23) The apparatus of claim 22 wherein the one or more modules are capable of imposing a flow of fluid across the wound bed which is parallel flow, radial streaming, spiral streaming, helical streaming, spirohelical streaming or circular streaming.

24) The apparatus of claim 22 or 23 wherein the one or more modules comprise a plurality of inlet and/or outlet pipes disposed in an array under the wound-facing face of the dressing, so as to allow passage of irrigant and/or wound exudate through the wound to take place in a controllable linear stream.

25) The apparatus of any one of claims 22 to 24 wherein the one or more modules comprise arrays of inlet pipe(s) and/or outlet pipe(s) under the wound-facing face of the wound dressing which are aligned parallel to each other, opposing each other diametrically across the wound.

26) The apparatus of any one of claims 22 to 25 wherein the one or more modules comprise irrigant inlet and/or outlet manifolds with respectively a plurality of inlet and/or outlet apertures or pores which are connected to at least one irrigant inlet pipe(s) and/or outlet pipe(s) under the wound-facing face of the wound dressing.

27) The apparatus of anyone of claims 22 to 26 wherein the one or more modules comprise an irrigant inlet manifold and an aspirate outlet arranged opposite each other in the wound bed.

28) The apparatus of any one of claims 22 to 27 wherein the one or more modules and backing are integral.

29) The apparatus of any one of claims 22 to 27 wherein the one or more modules and backing are separate integers.

30) The apparatus of any one of claims 22 to 26 and 28 to 29 wherein the one or more modules are capable of imposing radial streaming.

31) The apparatus of claim 30 wherein the radial streaming is from the periphery of the wound bed to the centre of the wound bed.

32) The apparatus of claim 30 or 31 wherein the one or more modules comprise a plurality of inlet pipe(s) or outlet pipe(s) disposed to surround respectively one or more centrally disposed outlet or inlet pipes.

33) The apparatus of claim 32 wherein the one or more modules comprise at least one inlet or outlet aperture more-centrally disposed therein, and a plurality of corresponding outlet or inlet apertures disposed to surround the more-centrally disposed apertures.

34) The apparatus of claim 30 or 33 wherein the one or more modules comprise an inlet or outlet manifold disposed to surround a corresponding central outlet or inlet manifold or pipe.

35) The apparatus of claim 34 wherein the manifolds are fluid-inflatable bodies that lie in the wound in use and form projections.

36) The apparatus of any one of claims 26, 27, 34 and 35 wherein the manifolds are formed of porous film or microporous membrane.

37) The apparatus of any one of claims 26, 27, 34, 35 and 36 wherein the manifold has apertures or pores which are distributed evenly over the underside of the dressing and/or over the wound bed in use.

38) The apparatus of claim 37 wherein the apertures or pores form from 0.5 to 30% of the area of the wound-facing face of the dressing by the wound bed.

39) The apparatus of claim 37 or 38 wherein the apertures or pores have an average cross-dimension of from 1 to 1000μm.

40) The apparatus of any one of claims 37 to 39 wherein, in use the pressure differential across the apertures or pores is from 1 to 500 mmHg.

41) The apparatus of any preceding claim wherein the means for applying flow stress to the wound bed comprises projections and/or depressions on the wound-facing face of the dressing, that are capable of directing flow.

42) The apparatus of claim 41 wherein the projections or depressions run within the wound between an inlet pipe and or manifold and an outlet pipe or manifold on the wound-facing face of the wound dressing.

43) The apparatus of claim 41 or 42 wherein the projections may have a significantly three-dimensional structure, such as points, bosses, ribs and ridges.

44) The apparatus of claim 43 wherein the projections are bosses which are circular, elliptical or polygonal in plan view.

45) The apparatus of claim any one of claims 41 to 44 wherein the projections are fluid inflatable bodies.

46) The apparatus of claim 45 wherein the fluid inflatable bodies comprise inlet or outlet manifolds.

47) The apparatus of claim any one of claims 41 to 46 wherein the projections are provided in a substantially radiating array under the wound-facing face of the wound dressing, disposed regularly or irregularly across the dressing.

48) The apparatus of any one of claims 41 to 47 wherein the wound dressing comprises depressions have a significantly three-dimensional structure, such as grooves, channels or conduits.

49) The apparatus of any preceding claim wherein the apparatus comprises a pulsable valve on the fluid reservoir, and an electromechanical oscillator directly coupled to the wound dressing.

50) The apparatus of claim 3 wherein the means for simultaneous aspiration and irrigation of the wound comprises a first device for moving fluid through the wound applied to fluid downstream of and away from the wound dressing, in combination with at least one of

- a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing;
- means for aspirate flow regulation, connected to the fluid offtake tube; and
- means for supply flow regulation, connected to the fluid supply tube.

51) The apparatus of claim 50 wherein the first and/or second device for moving fluid through the wound is a variable-throughput device.

52) The apparatus of claim 51 wherein the first and/or second device is a variable-speed pump.

53) The apparatus of claim 52 wherein the first and/or second device for moving fluid through the is a reciprocating pump or a rotary pump.

54) The apparatus of claim 53 wherein the first device is a diaphragm pump.

55) The apparatus of claim 53 wherein the second device is a peristaltic pump.

56) The apparatus of any one of claims 50 to 55 wherein the variable-throughput device is capable of pulsed, continuous, variable and/or automated and/or programmable fluid movement.

57) The apparatus of any preceding claim wherein the apparatus is capable of applying a negative pressure within the wound dressing of up to 50% atm.

58) The apparatus of claim 57 comprising at least one body in the flow path to, over and from the wound bed which has sufficient resilience against the pressure to allow any significant compression or decompression of the fluid occur.

59) The apparatus of any preceding claim wherein securing means are provided to secure the wound dressing to the site of the wound.

60) A conformable wound dressing comprising:

- a backing layer with a wound-facing face which is capable of forming a relatively fluid-tight seal or closure over a wound
- at least one pipe which passes through and/or under the wound-facing face to allow irrigation and/or aspiration of the wound,
- the point at which the at least one pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound in use;

characterised in that

- the wound dressing comprises means for means for applying flow stress to the wound bed.

61) The wound dressing of claim 60 provided in a bacteria-proof pouch.

62) A method of operation of an apparatus for aspirating, irrigating and/or cleansing a wound, said method comprising the steps of:

a) providing the apparatus of any one of claims 1 to 59;
b) applying the wound dressing to the wound;
c) conforming the backing layer of the wound dressing to the shape of the bodily part in which the wound is to form a relatively fluid tight seal or closure;
d) activating at least one device for moving fluid through the wound dressing to the wound and/or from the wound to cause irrigant to move to the wound; and
e) activating means for applying flow stress to the wound bed.

63) The method of claim 62 wherein step (e) comprises activating means to provide:

a) a linear flow of irrigant across the wound bed,
b) a relatively high rate of irrigant flow across the wound bed, or
c) a combination of the two.

64) The method of claim 62 or 63 wherein application of flow stress to the wound bed is continuous.

65) The method of claim 62 or 63 wherein application of flow stress to the wound bed is intermittent.

66) The method of claim 65 wherein the intermittent application is made for from 1 to 4 times daily.

67) The method of claim any one of claims 62 to 66 wherein the wound dressing comprises an inlet and an outlet pipe and step (d) comprises the activating the at least one device of moving fluid through the wound dressing to move fluid through the at least one inlet and out of the at least one outlet pipe.

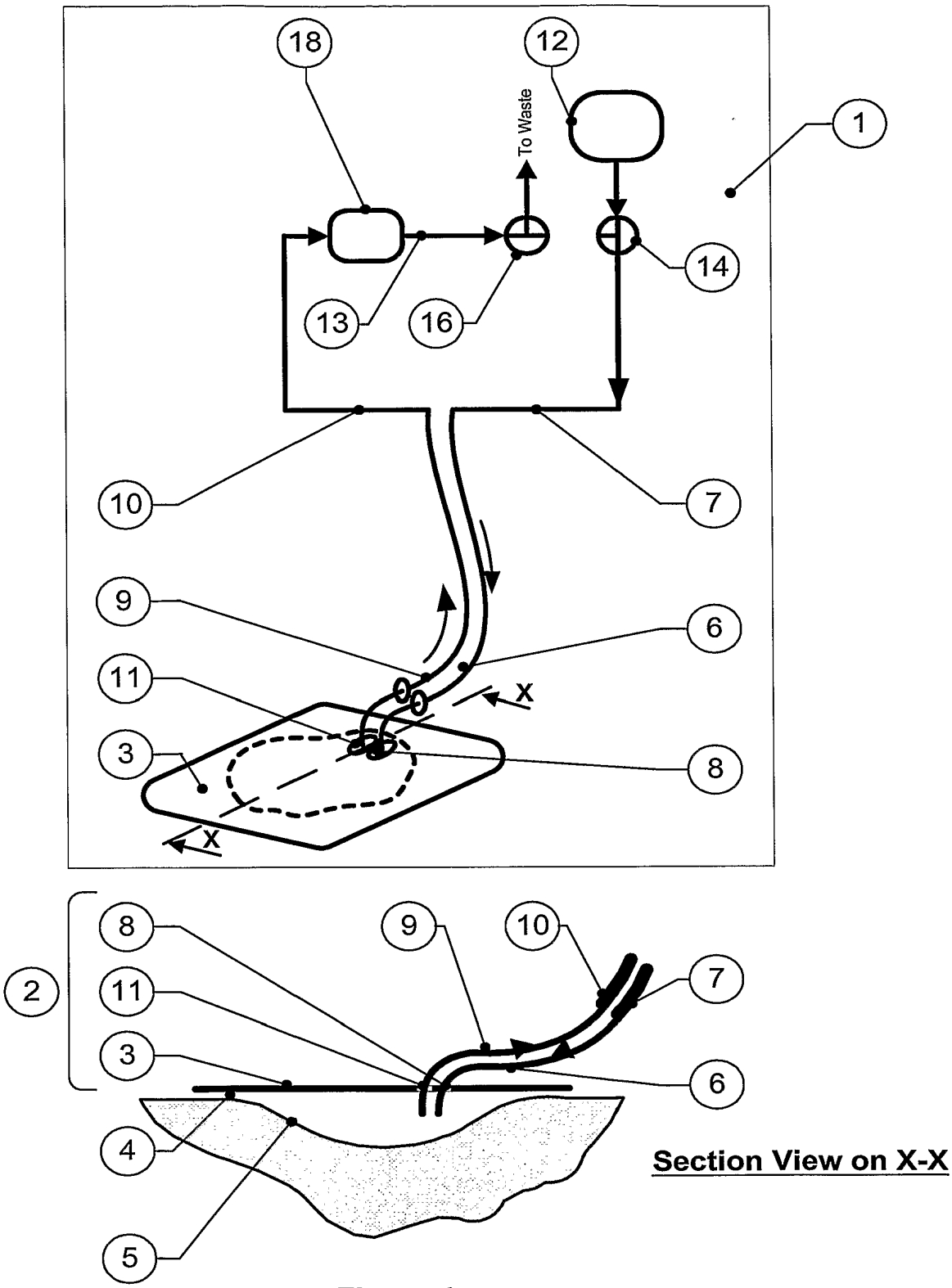
68) The method of any one of claims 62 to 67 wherein the flow rate of fluid to the wound is in the range of 1 to 1500 ml/hr.

69) The method of any one of claims 62 to 68 wherein the flow rate of total fluid out of the wound is in the range of 1 to 2000 ml/hr.

70) The method of any one of claims 67 to 69 wherein step (d) comprises activating simultaneous irrigation and aspiration of the wound.

71) The method of any one of claims 67 to 69 wherein step (d) comprises activating sequential irrigation and aspiration of the wound.

72) The method of any one of claims 62 to 71 wherein the apparatus is run at a negative pressure of up to 50% atm.


18
12
To Waste
1
14
13
16
10
7
9
6
11
X
3
8
X
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Section View on X-X

Figure 1

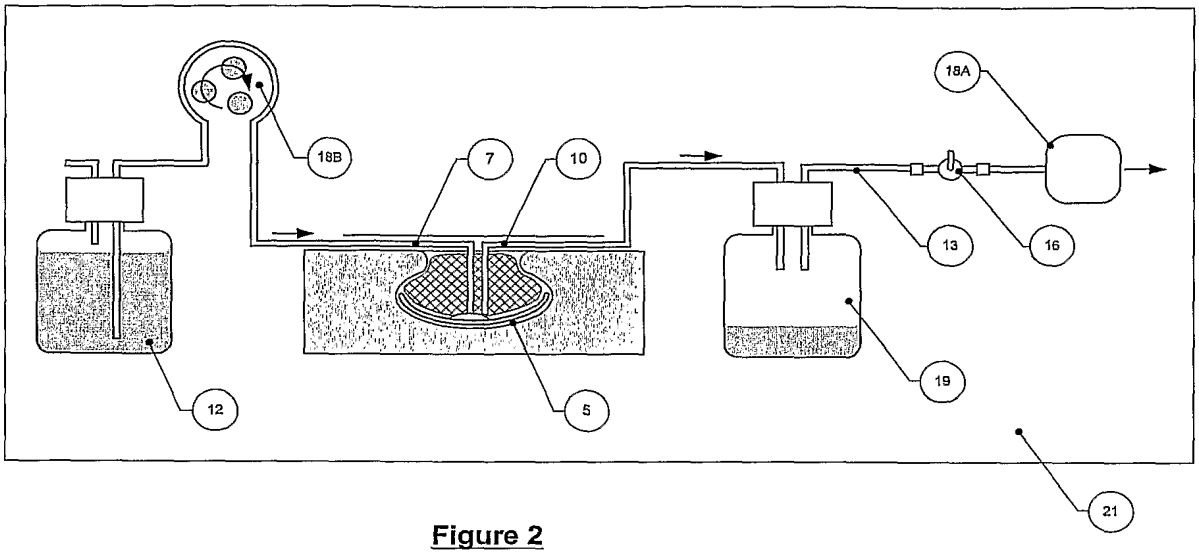


Figure 2

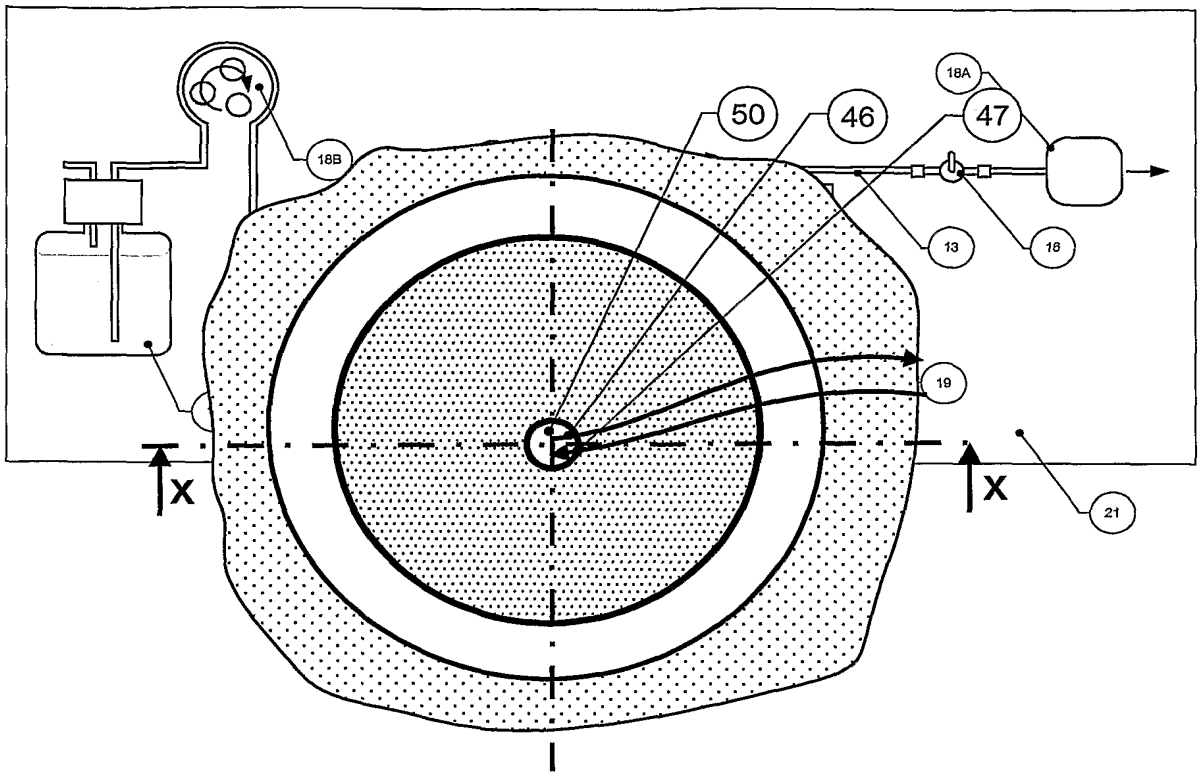


Figure 3a

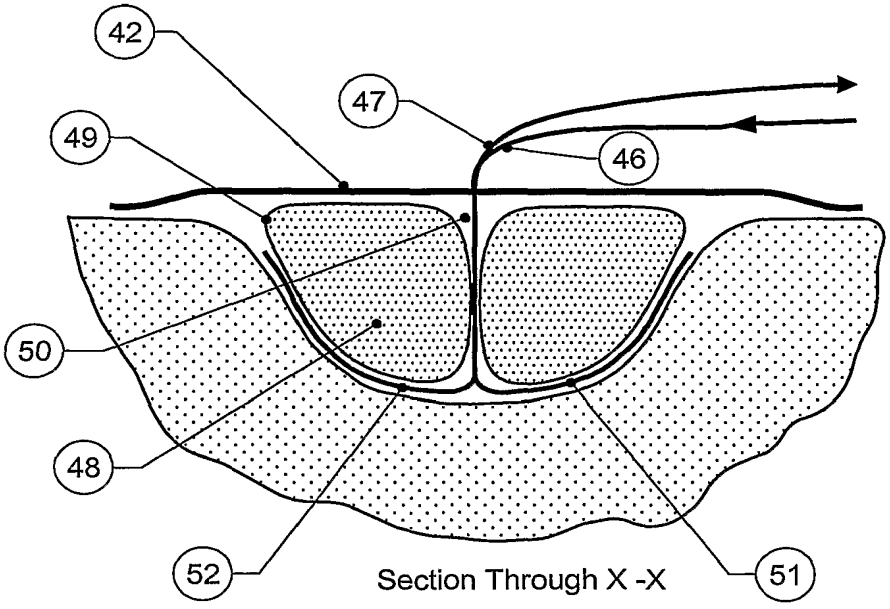


Figure 3b

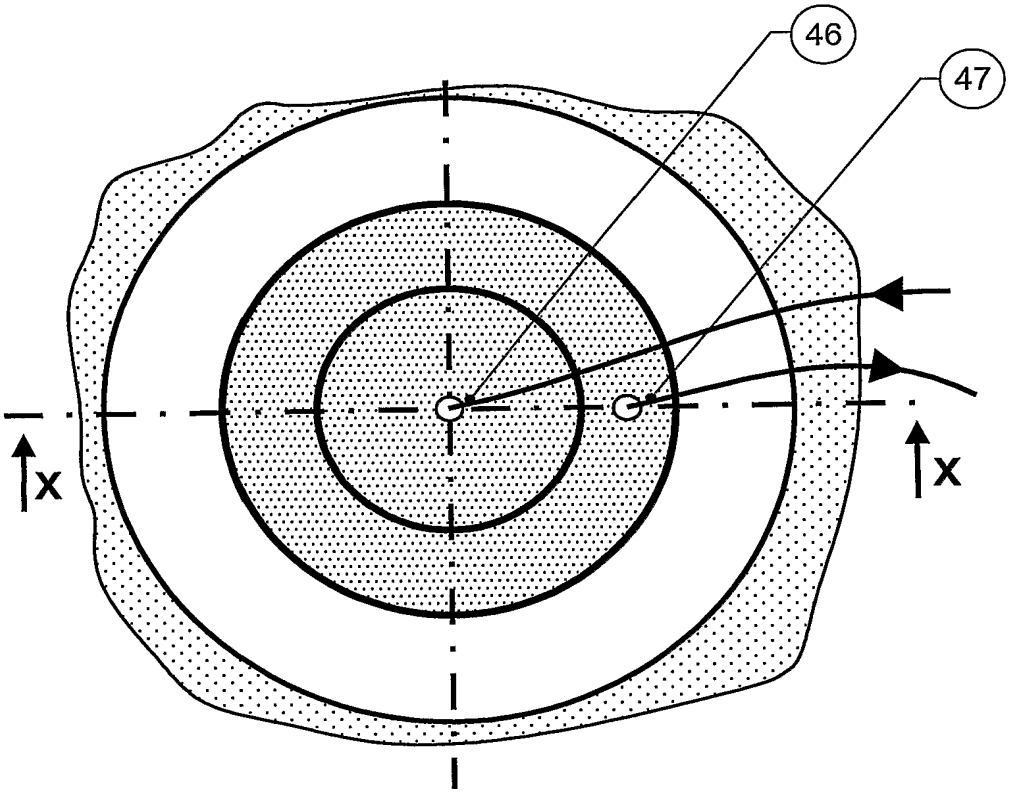


Figure 4a

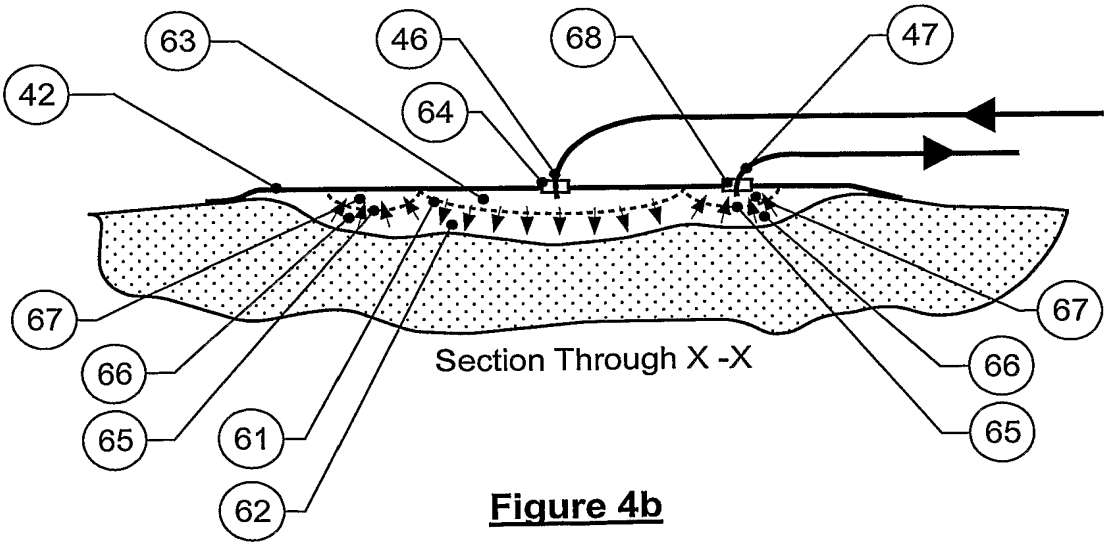


Figure 4b

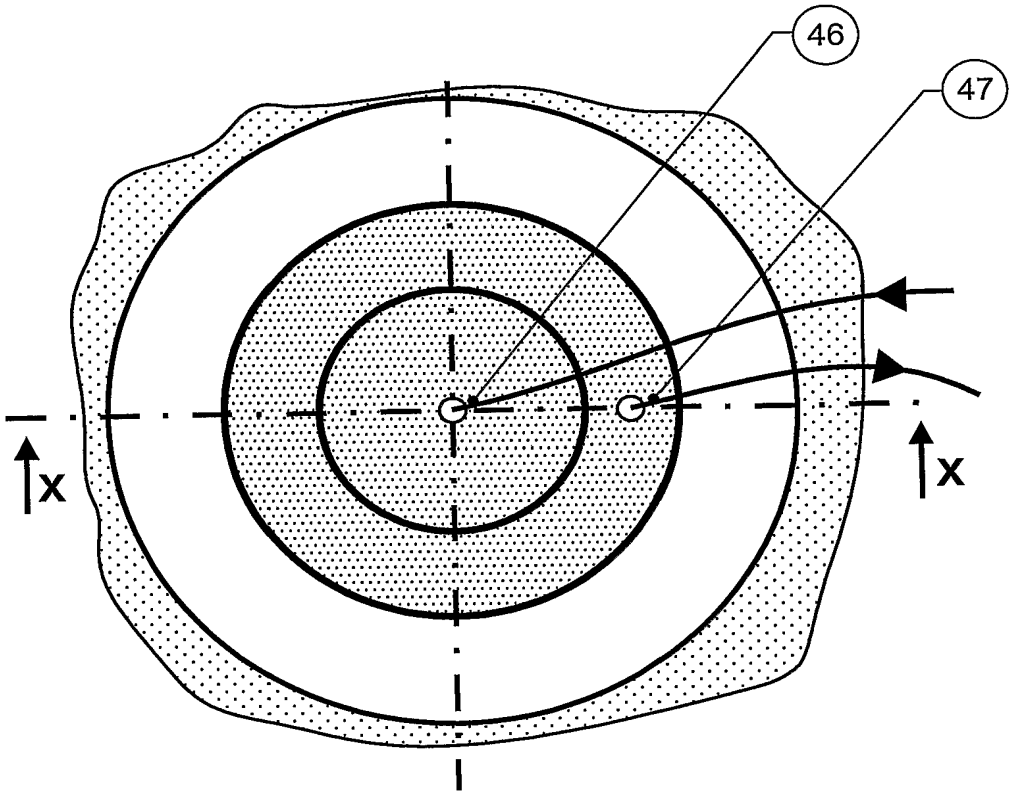


Figure 5a

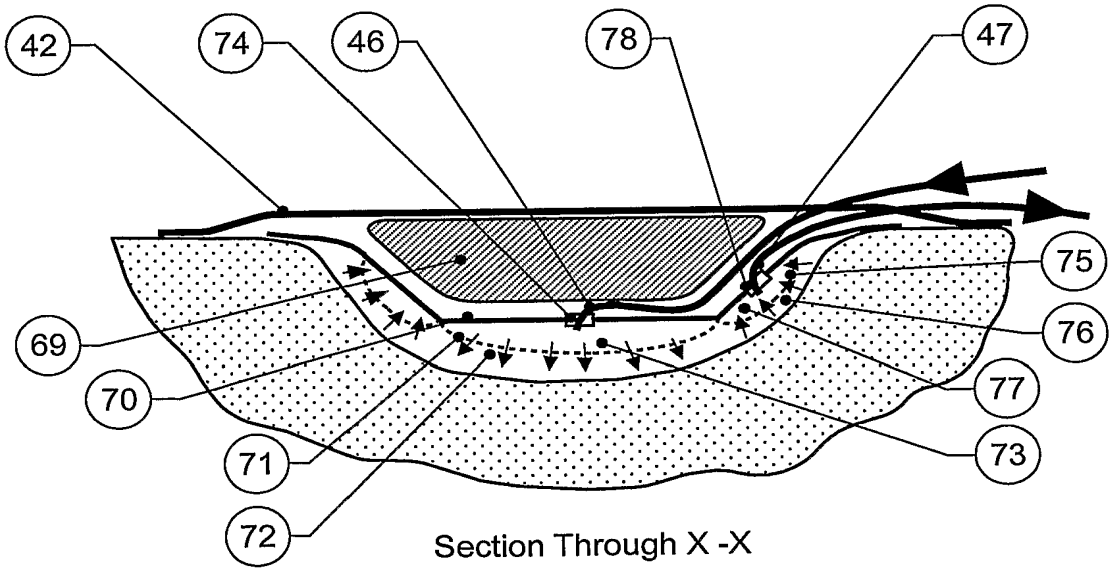


Figure 5b

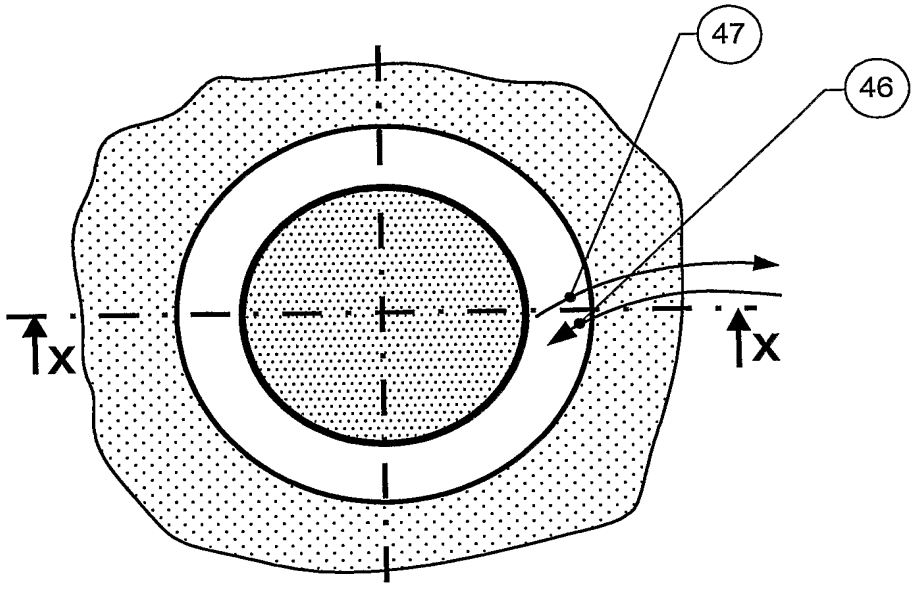


Figure 6a

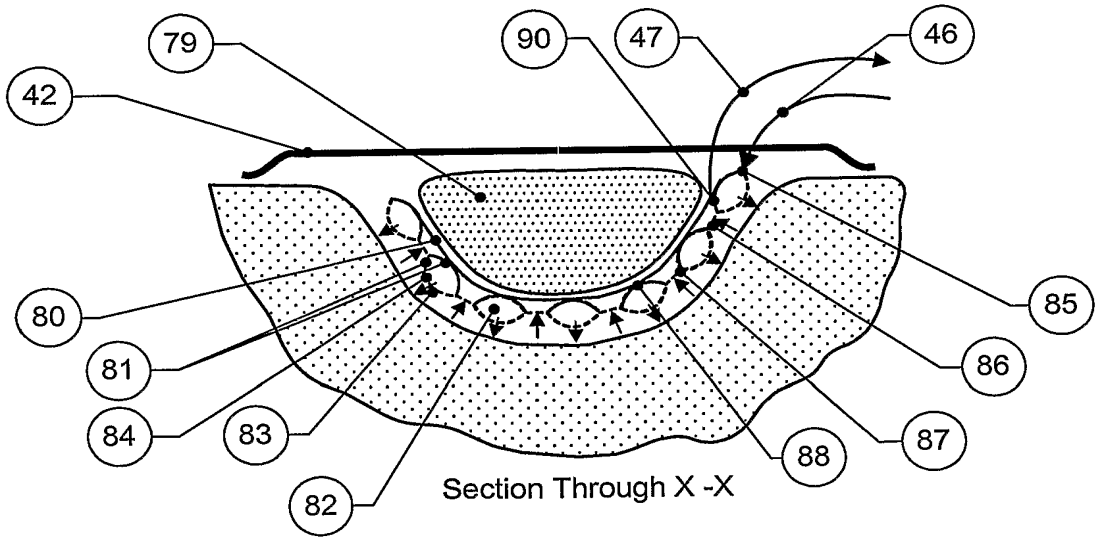


Figure 6b

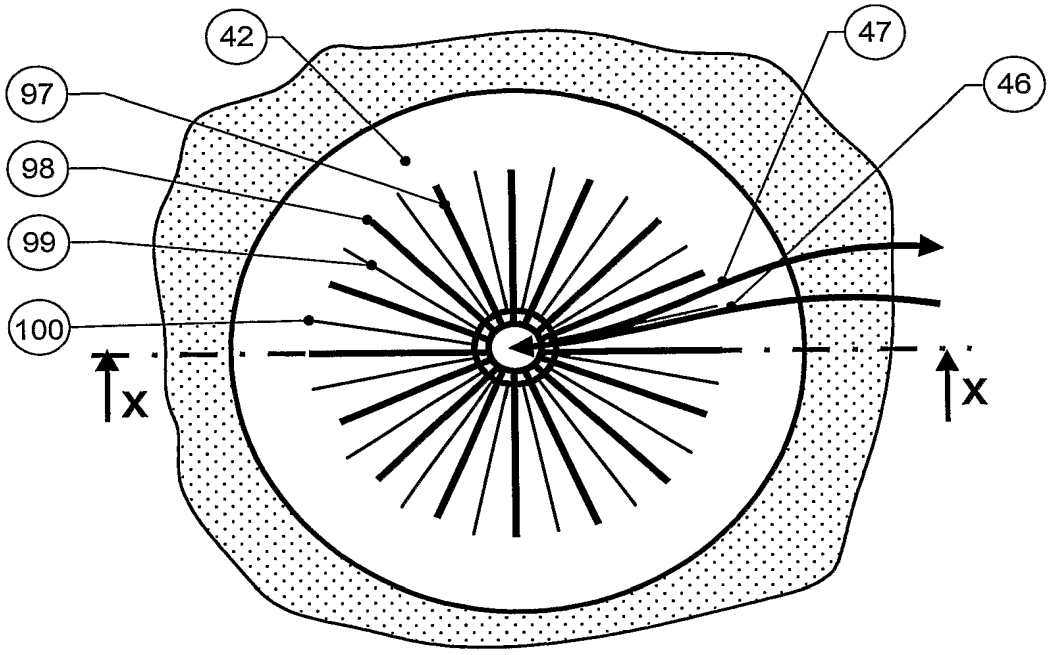


Figure 7a

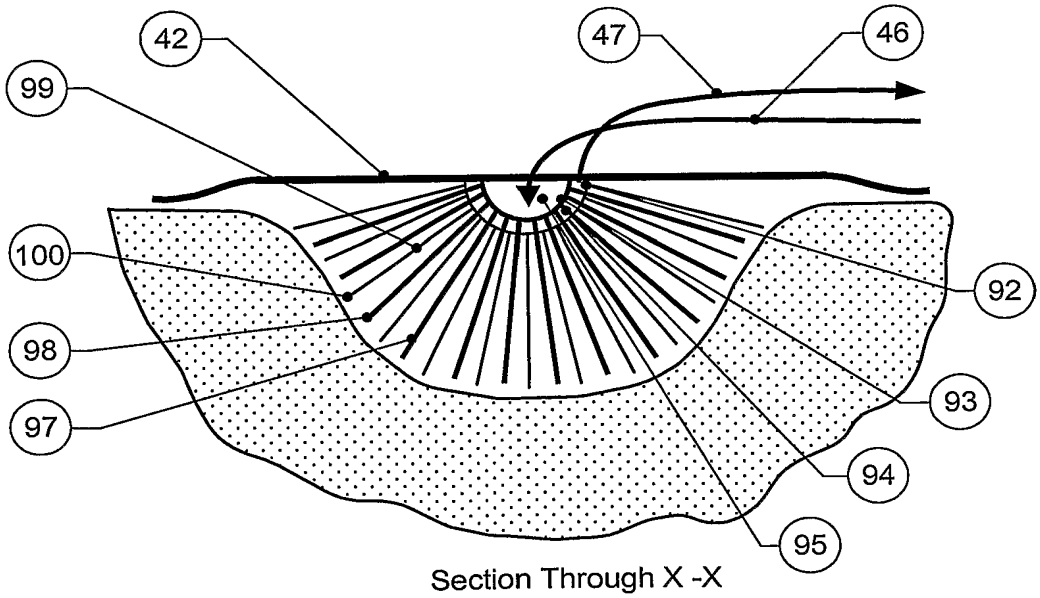


Figure 7b

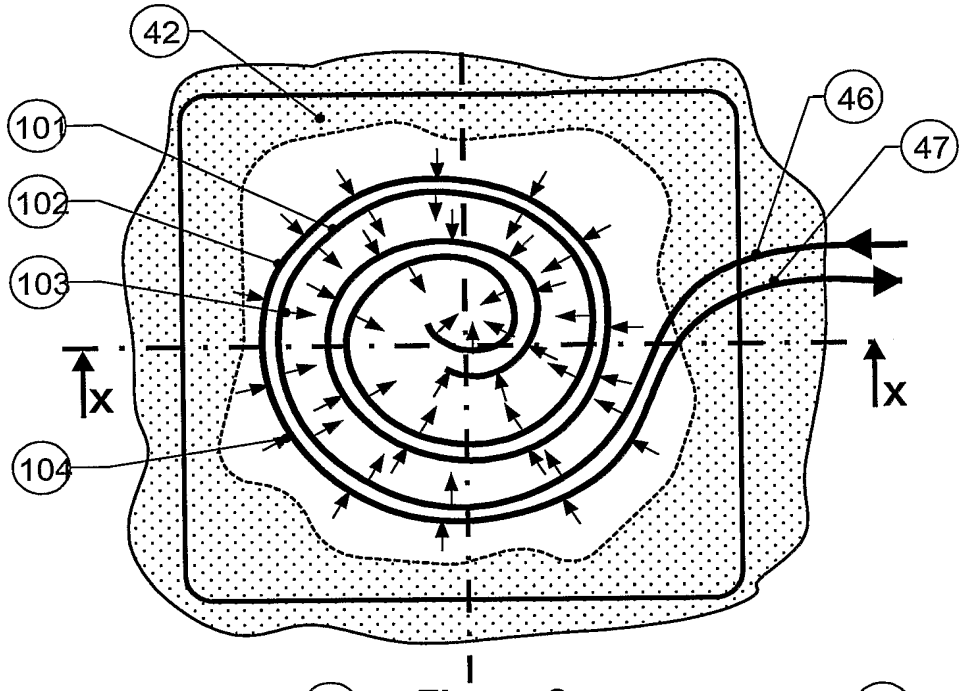


Figure 8a

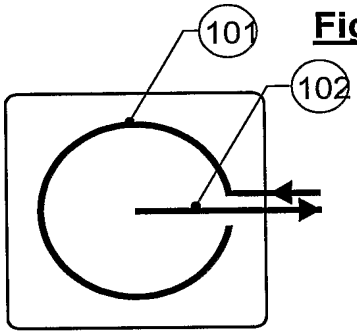


Figure 8b

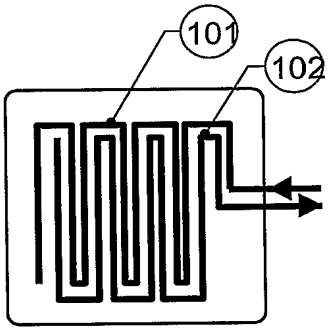
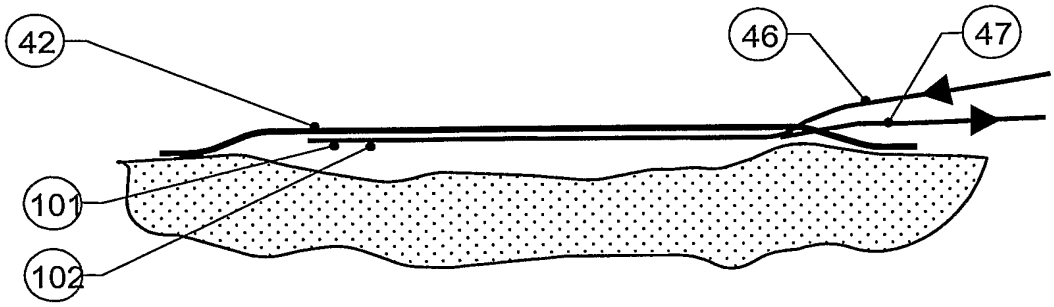


Figure 8c



Section Through X -X

Figure 8d

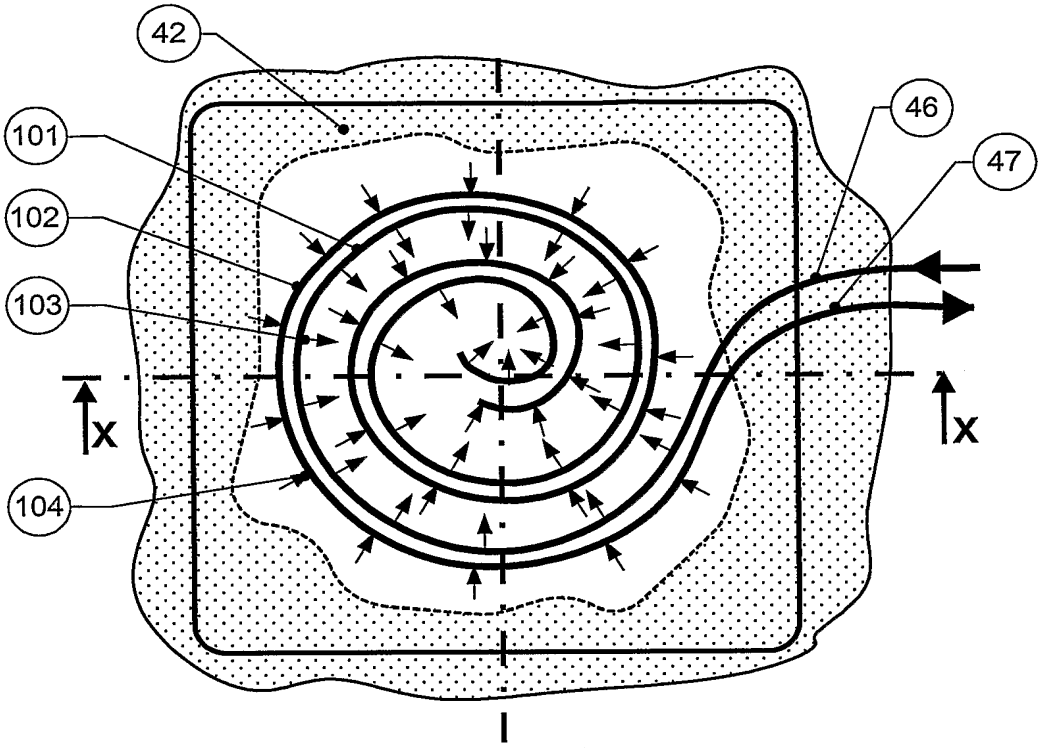
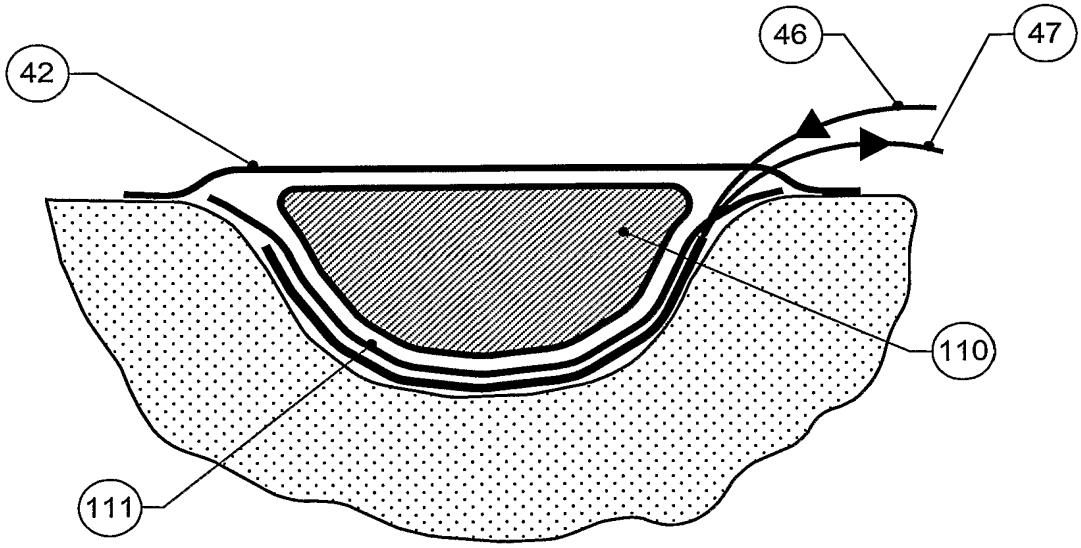
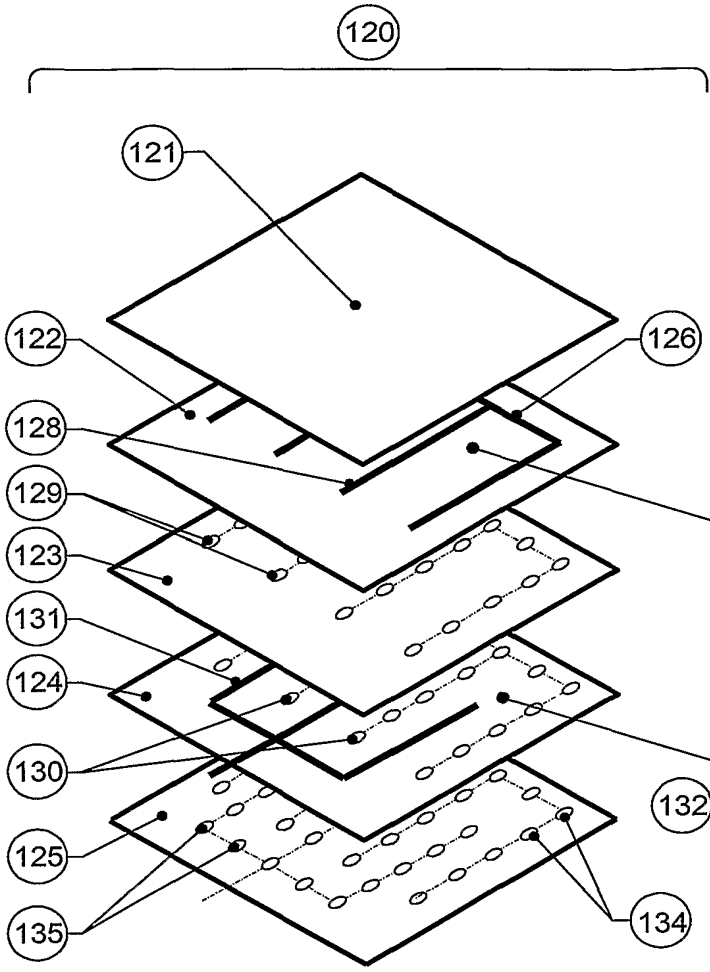


Figure 9a



Section Through X -X

Figure 9b



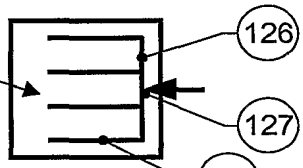


Figure 10b

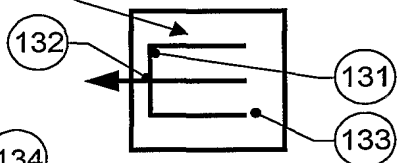


Figure 10c

Figure 10a

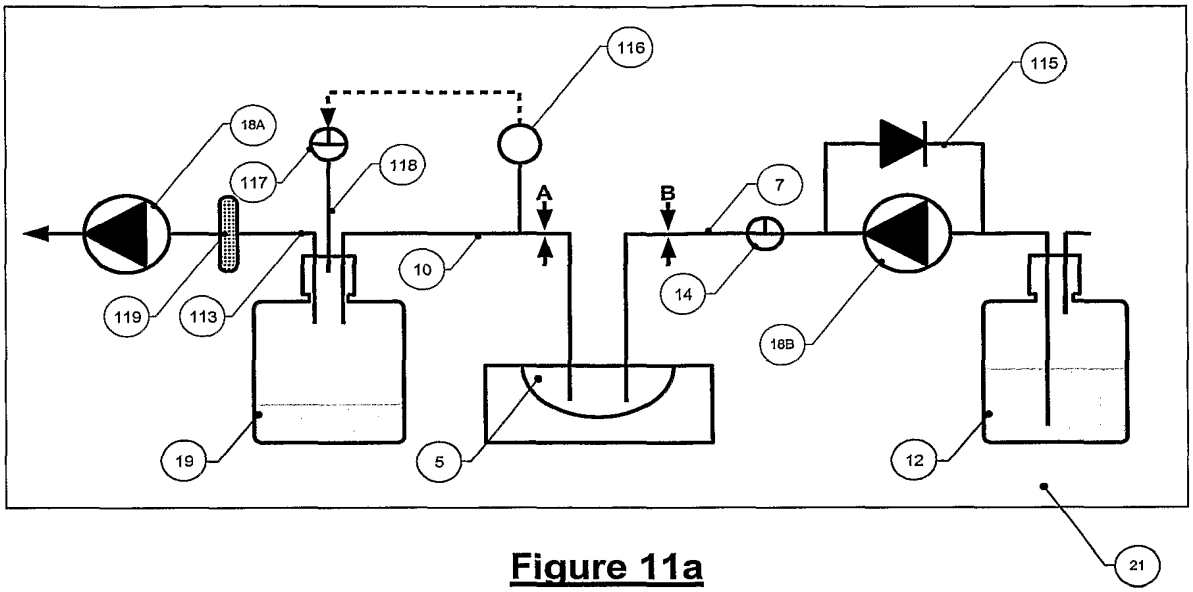


Figure 11a

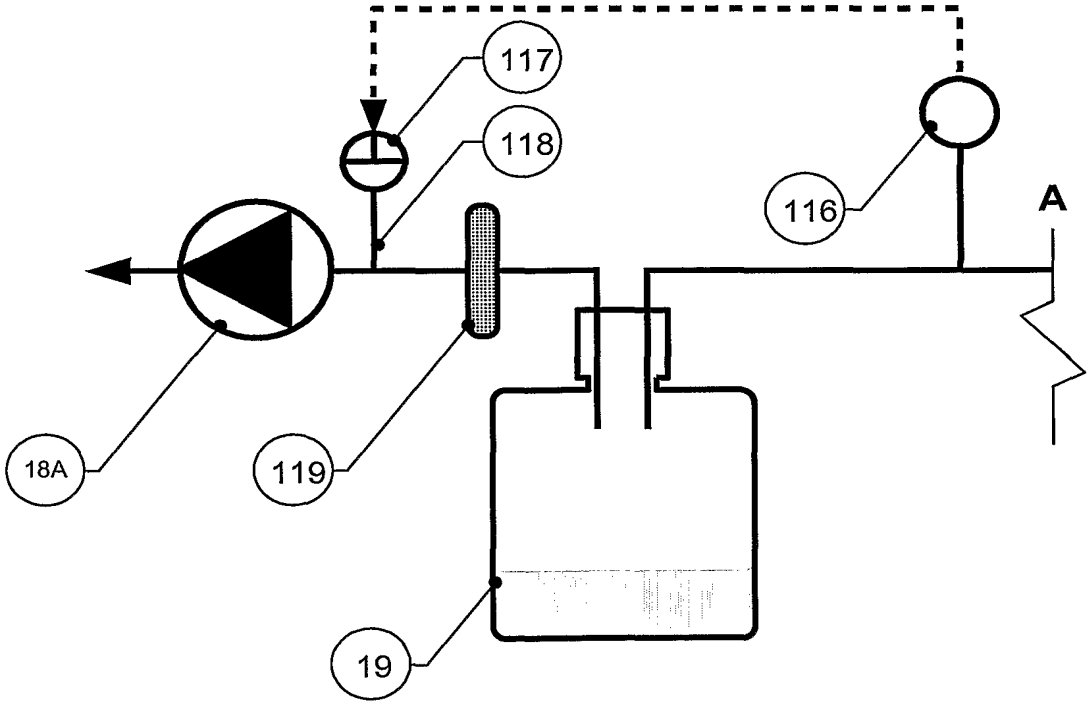


Figure 11b

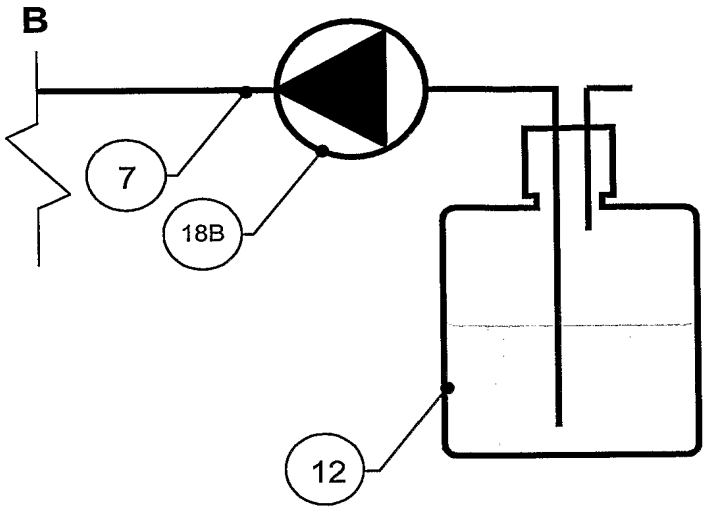


Figure 11c

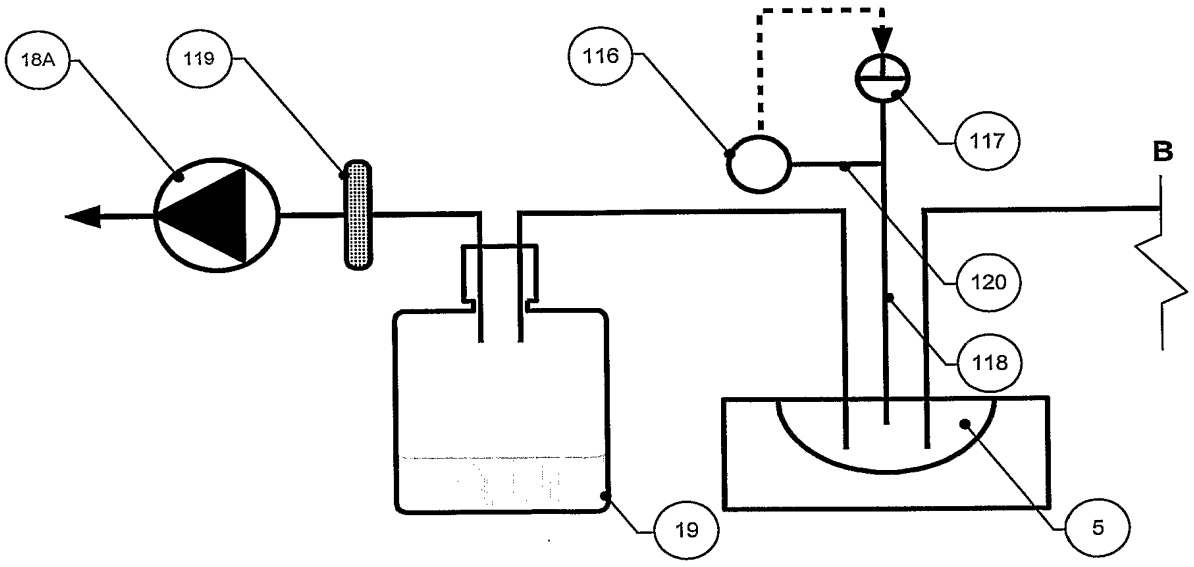


Figure 11d

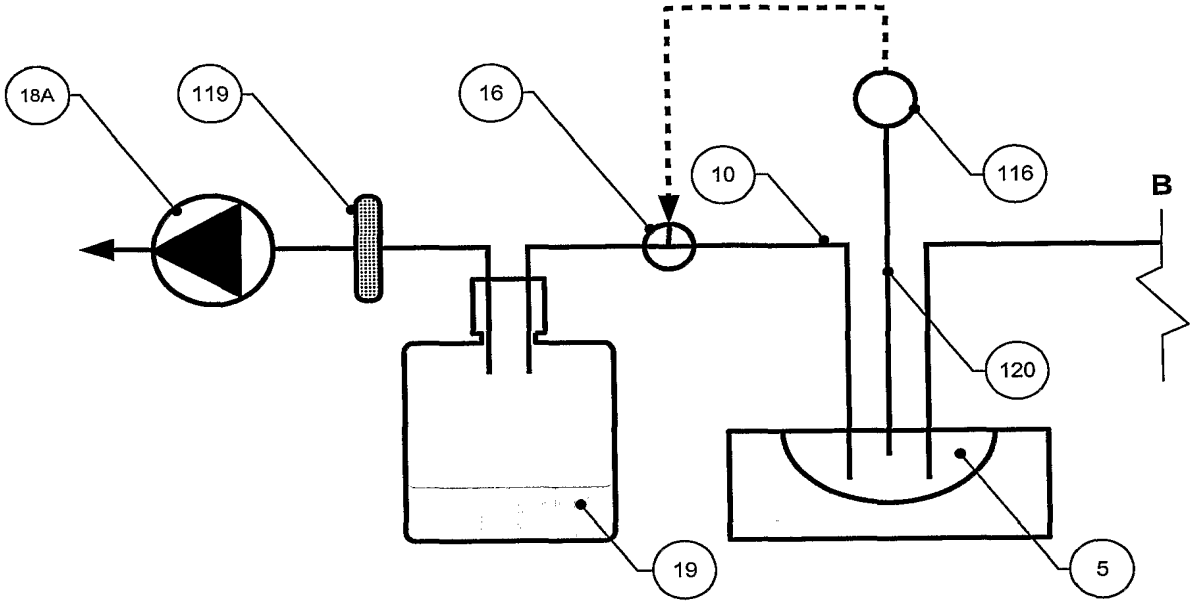


Figure 12a

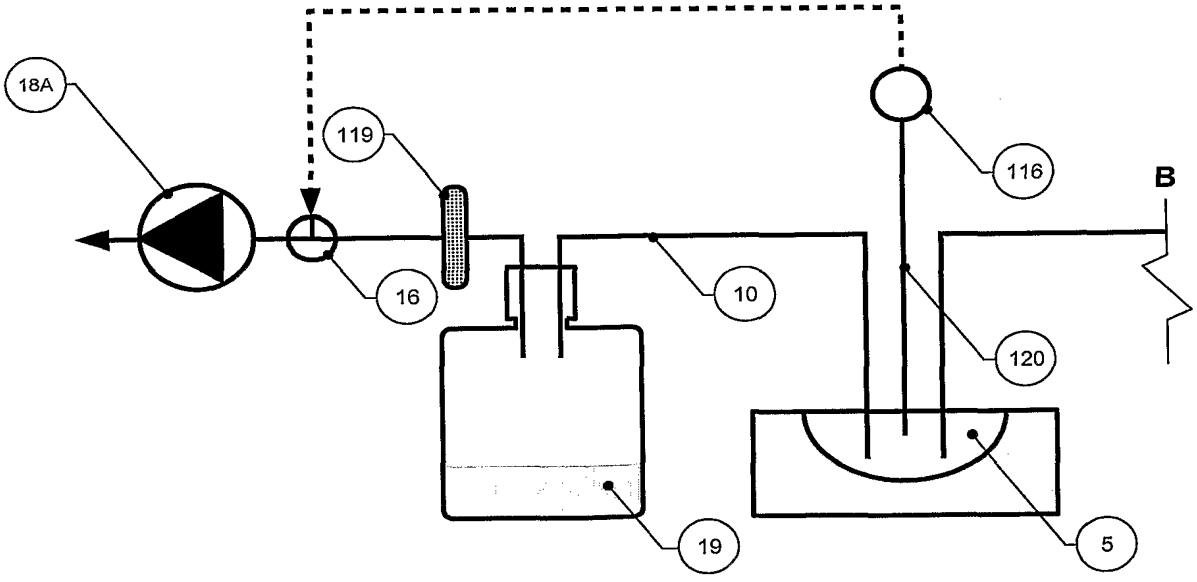


Figure 12b

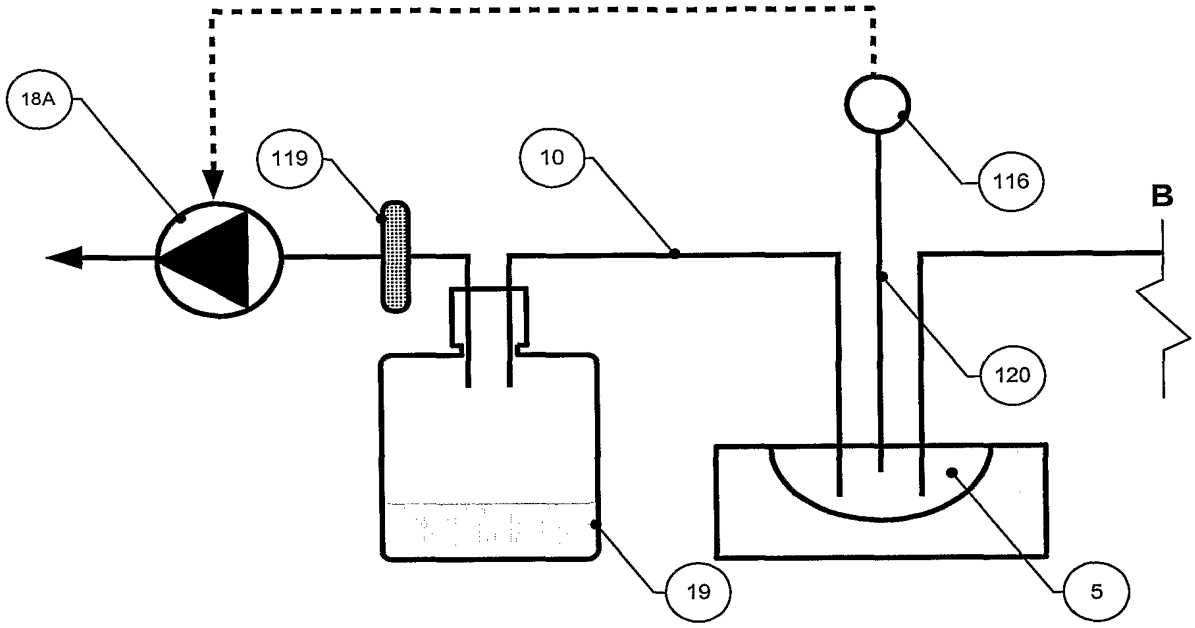


Figure 12c

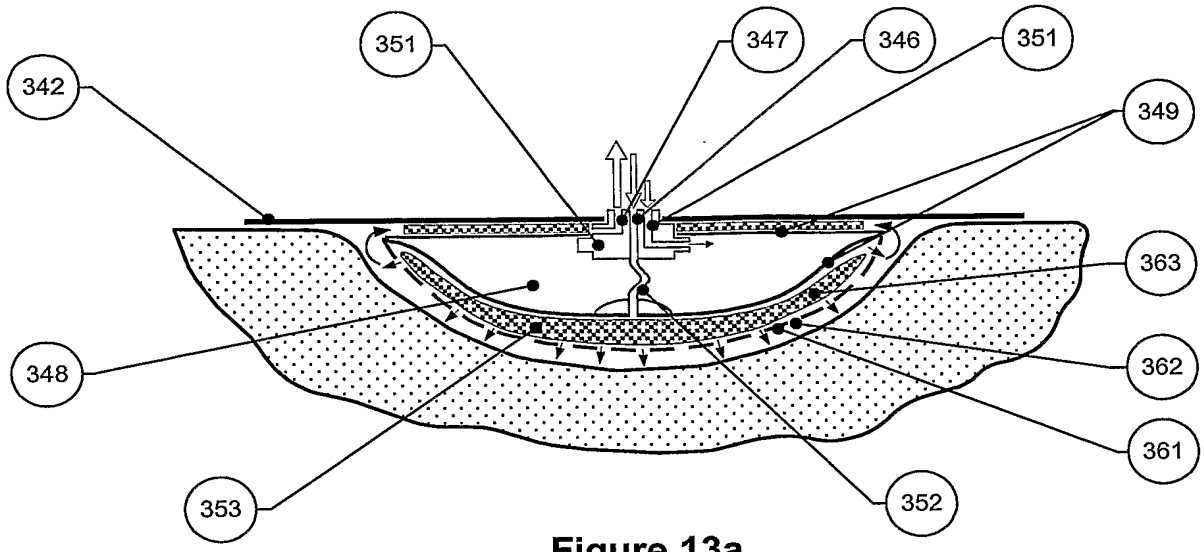


Figure 13a

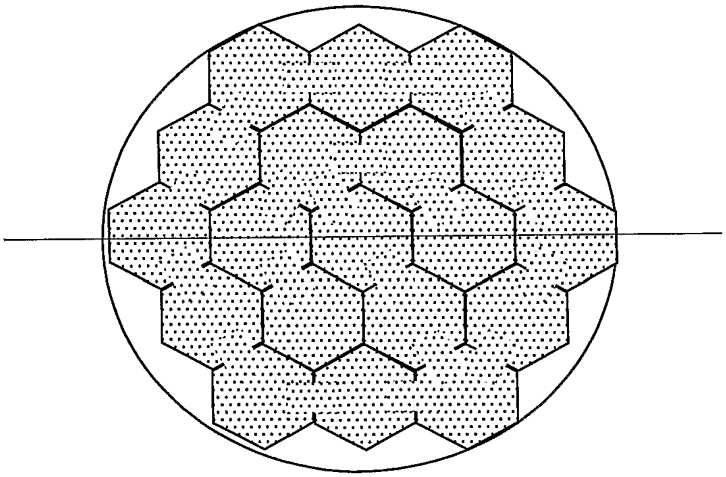


Figure 13b

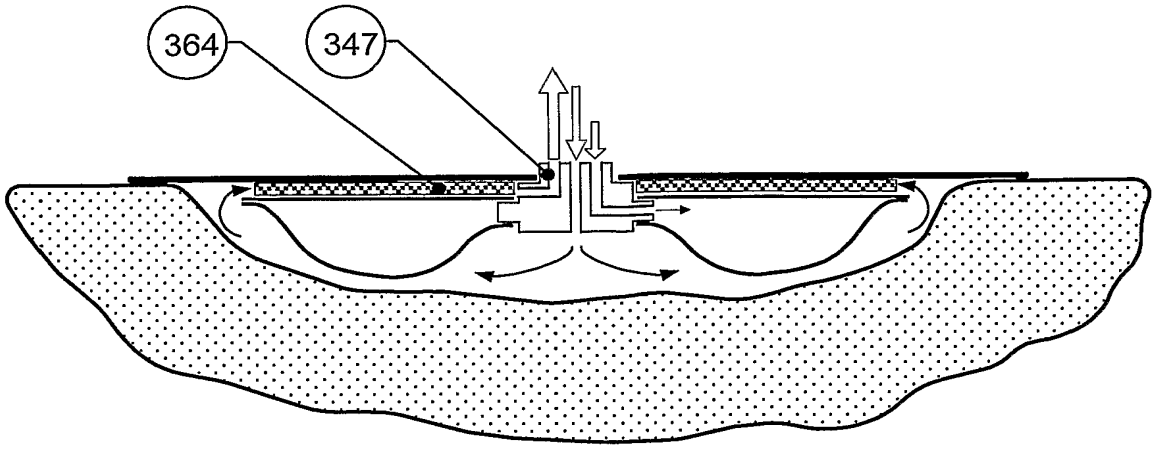


Figure 14

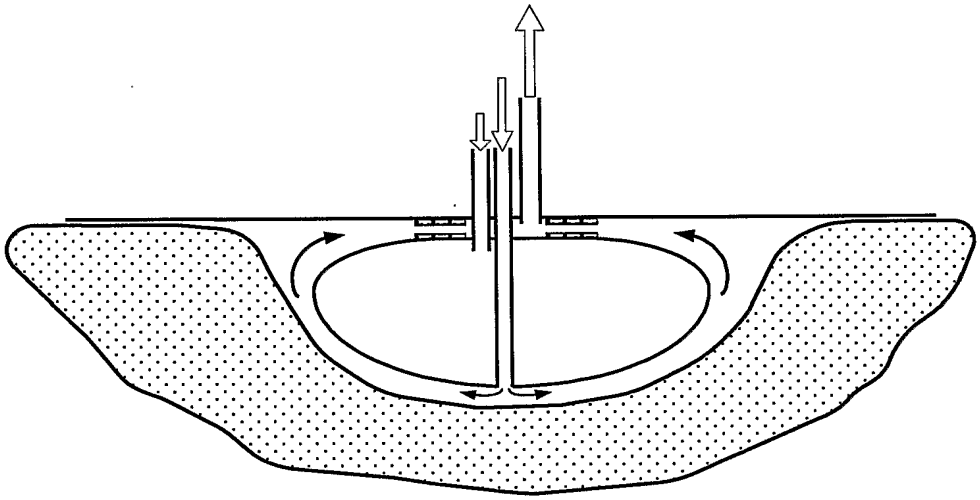


Figure 15

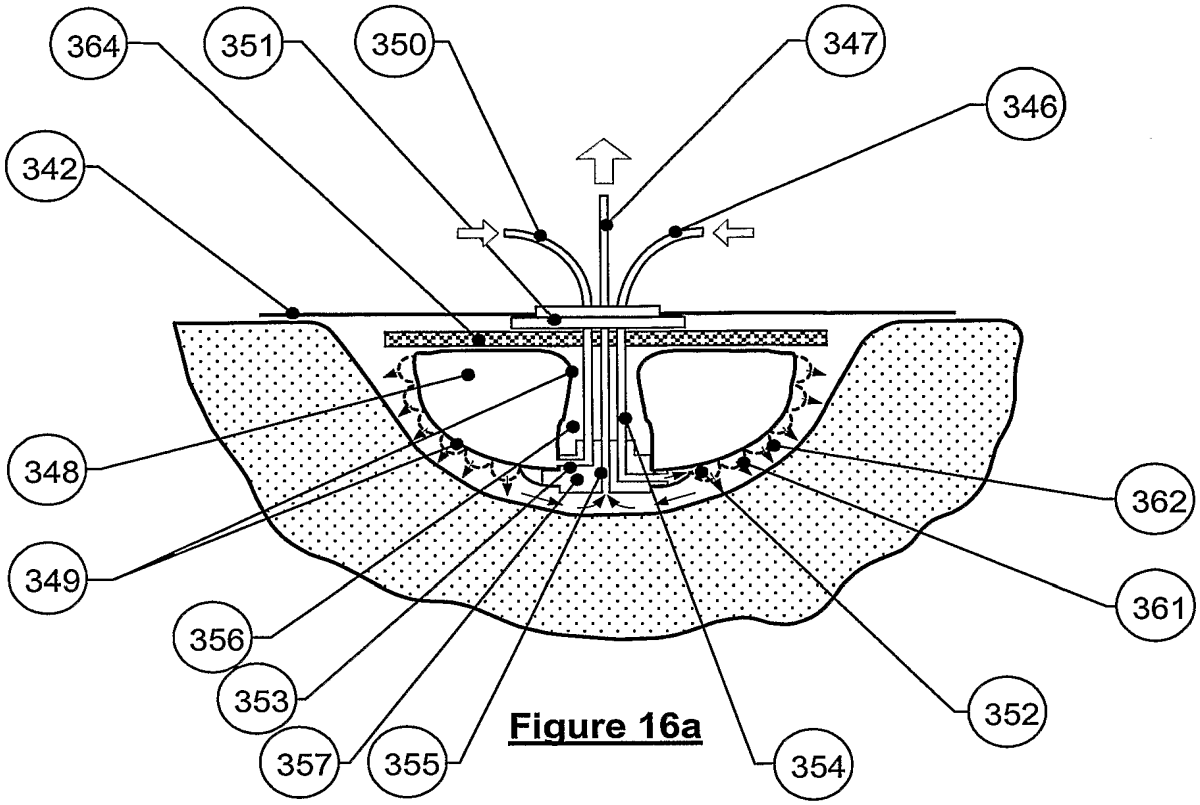


Figure 16a

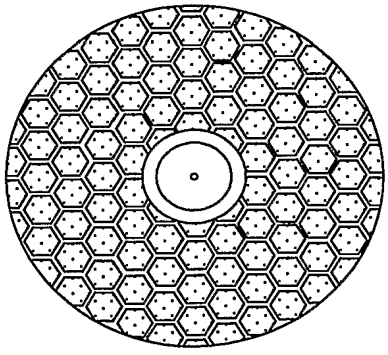


Figure 16b

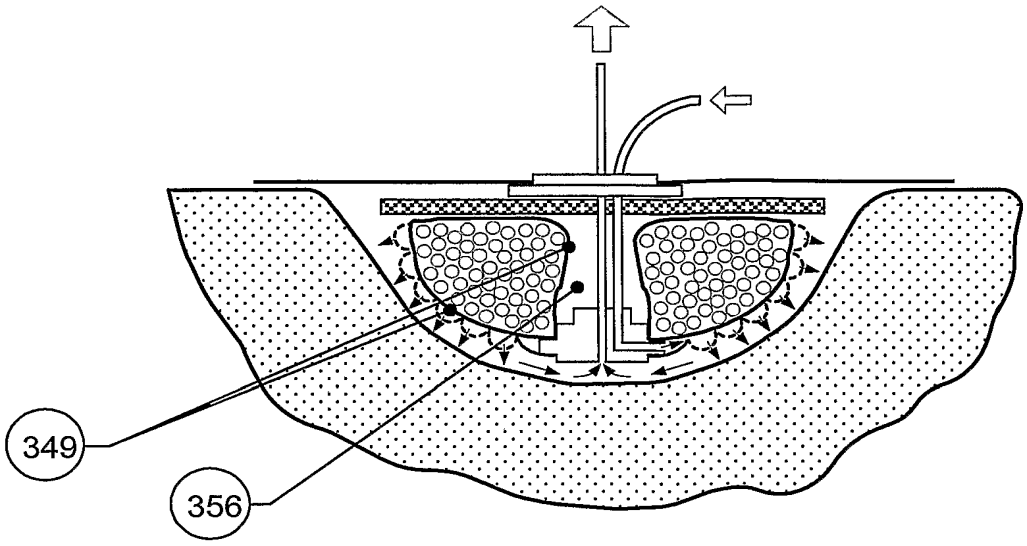


Figure 17

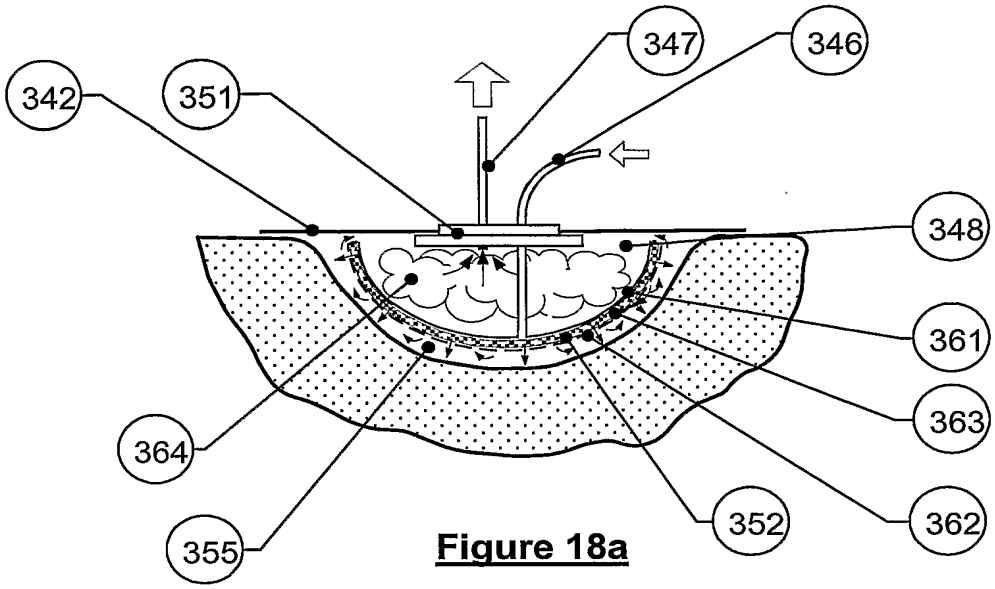


Figure 18a

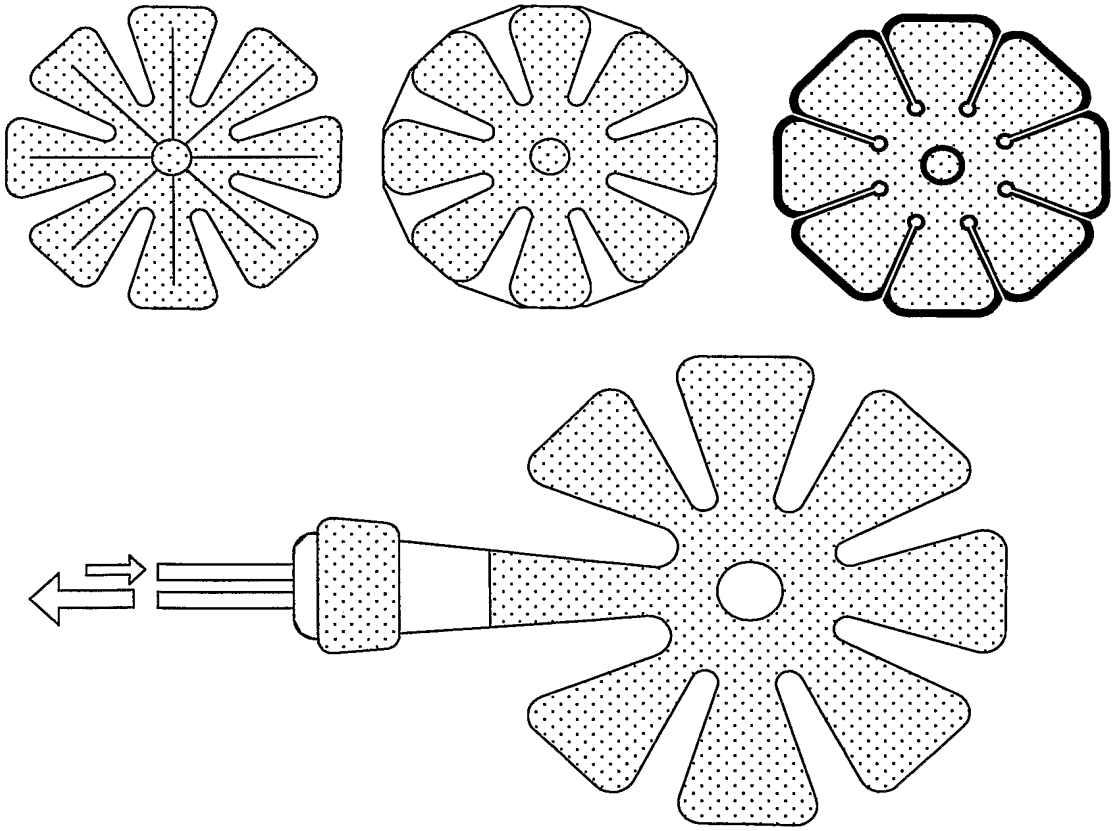


Figure 18b

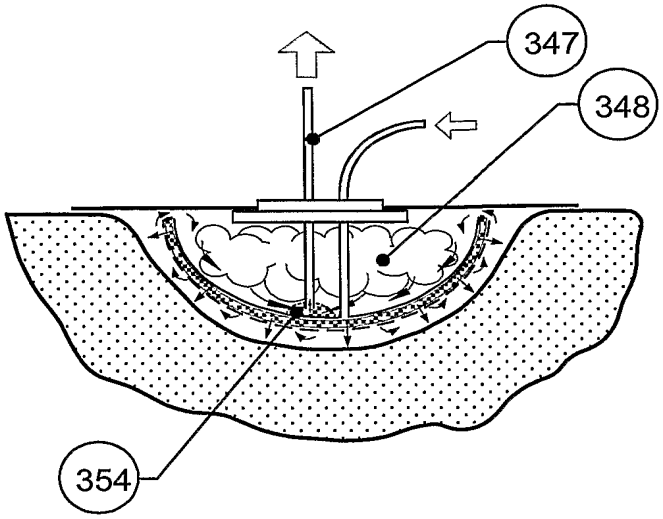


Figure 19

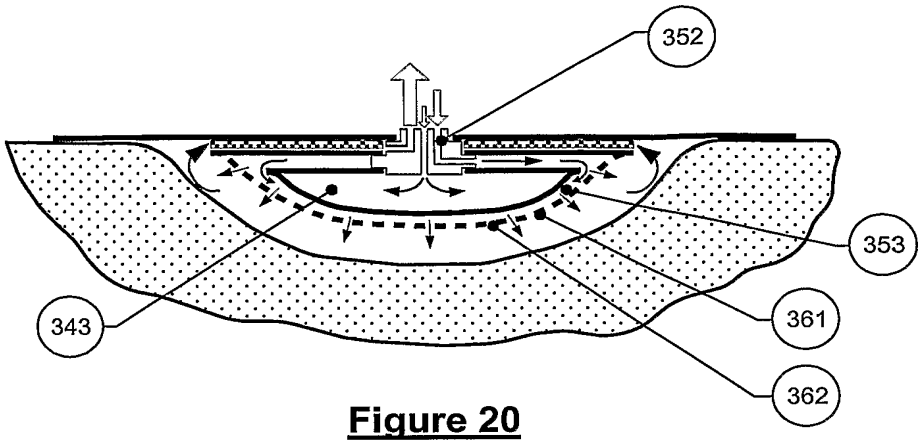


Figure 20

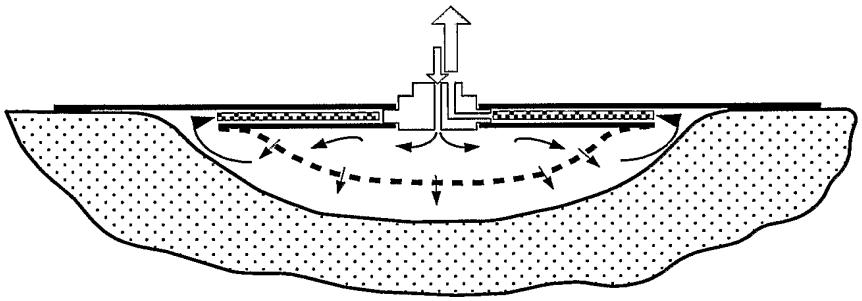


Figure 21

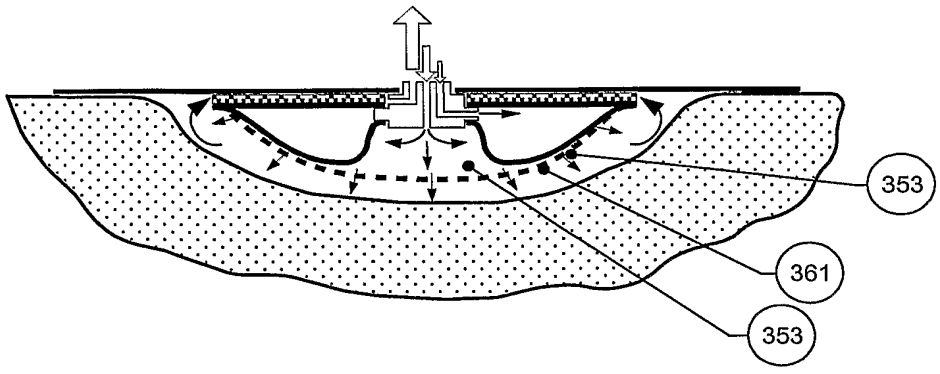


Figure 22

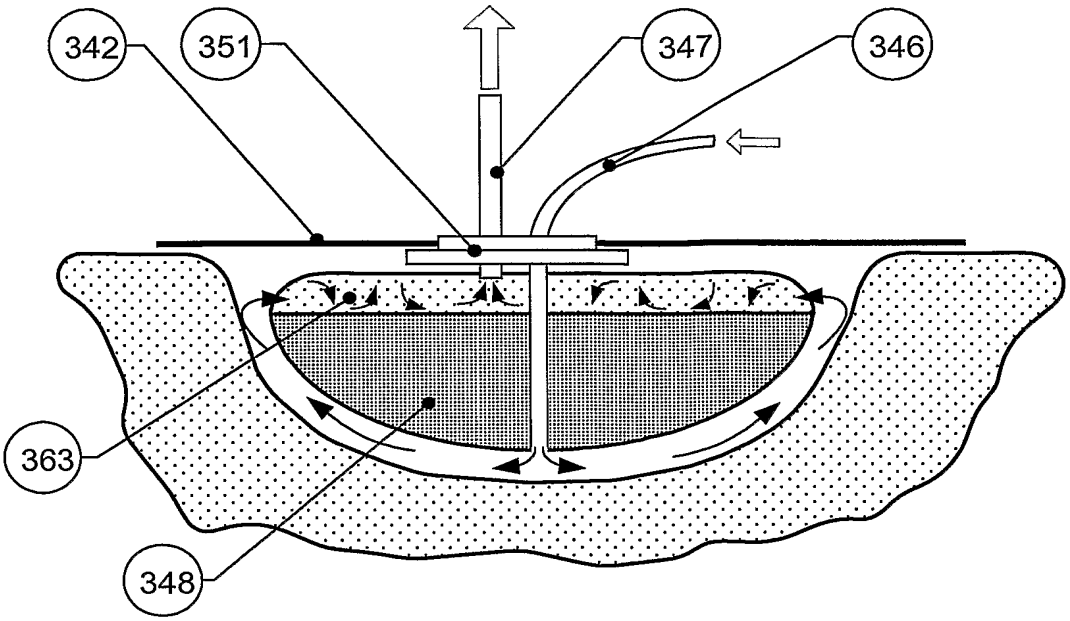


Figure 23

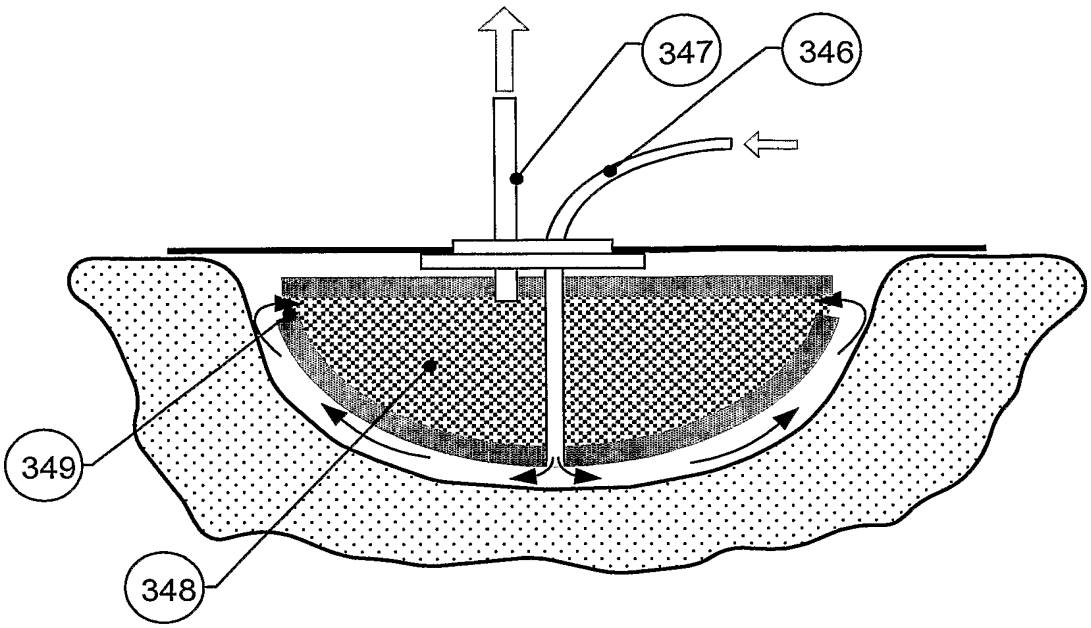


Figure 24

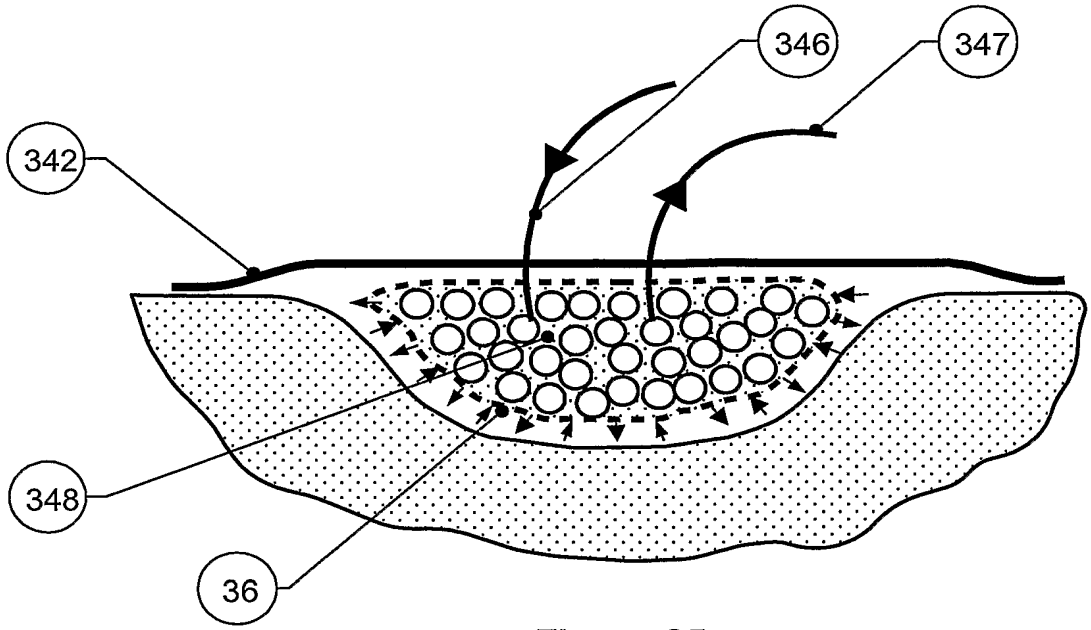


Figure 25

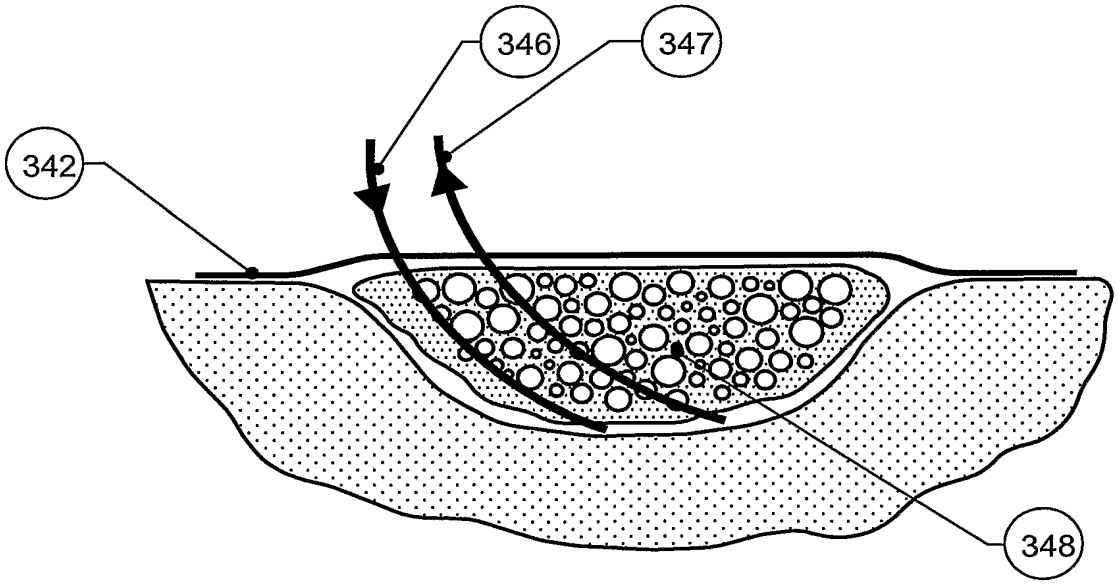


Figure 26

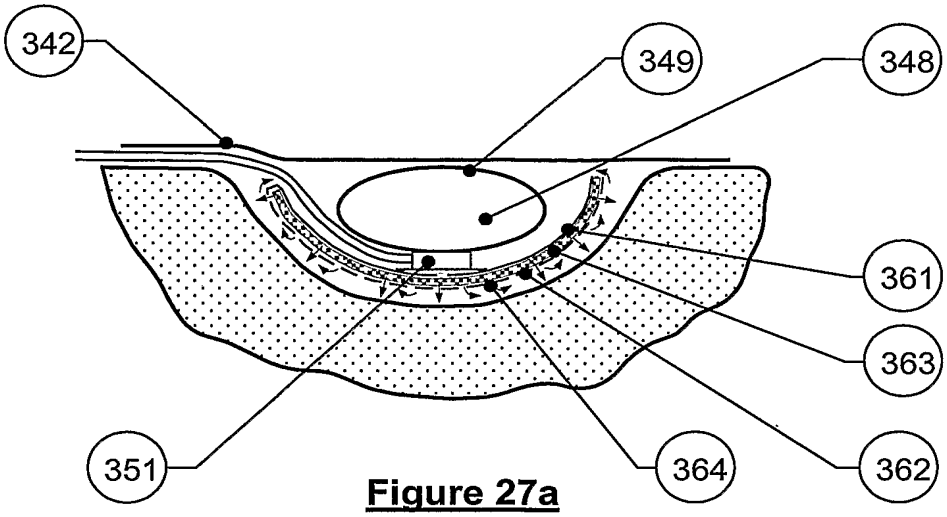


Figure 27a

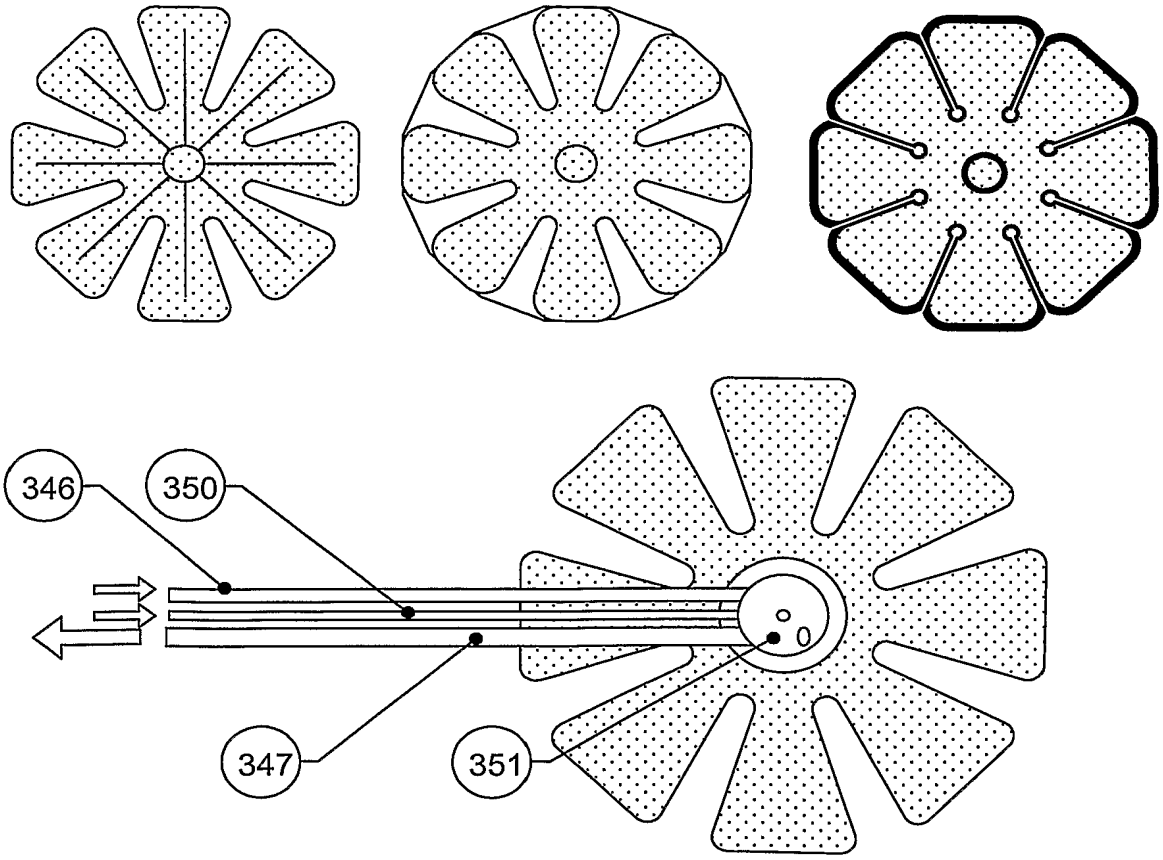


Figure 27b

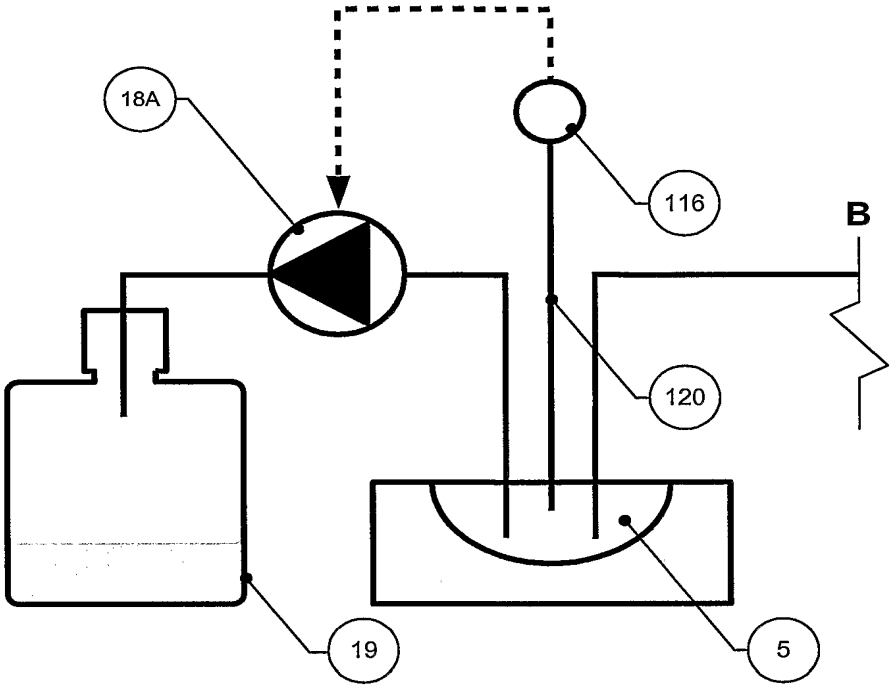


Figure 28a

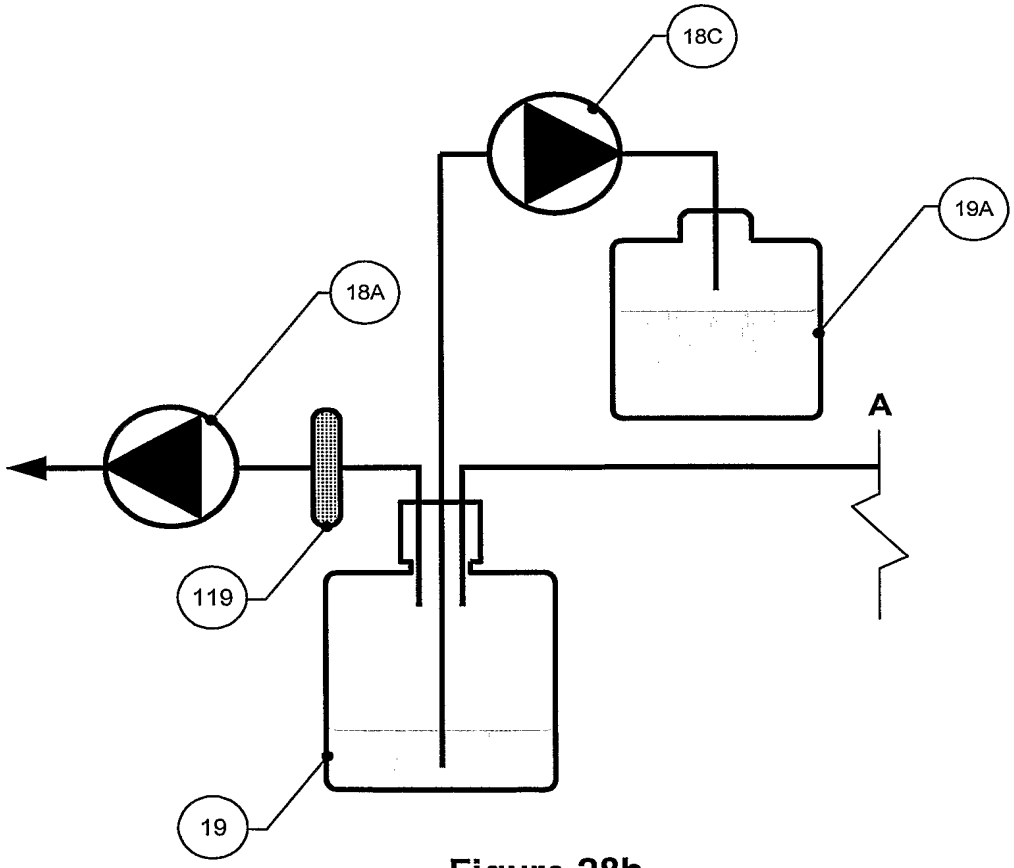


Figure 28b

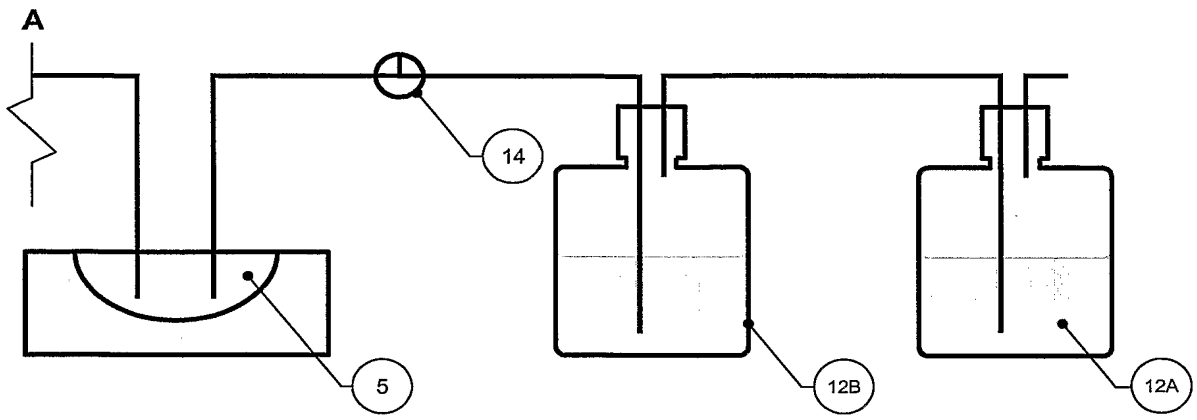


Figure 29

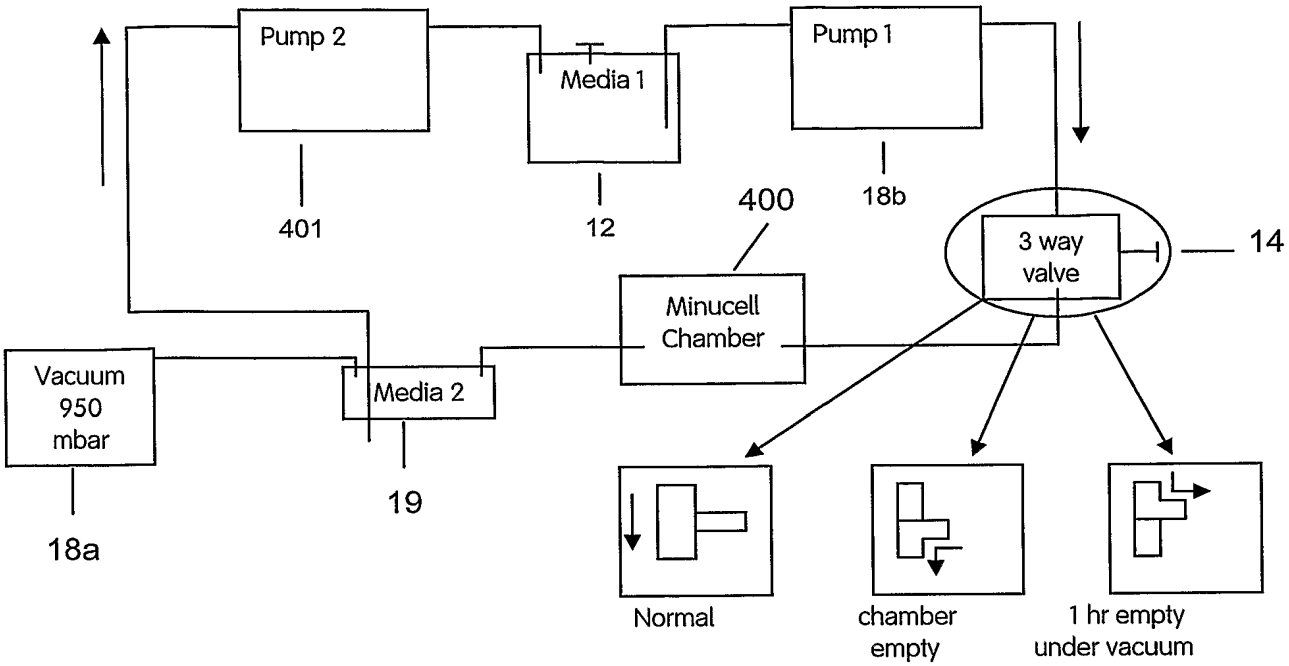

Pump 2
Media 1
Pump 1
401
12
400
18b
3 way valve
14
Minucell Chamber
Vacuum 950 mbar
Media 2
19
18a
Normal
chamber empty
1 hr empty under vacuum

Figure 30